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Supreme Court, U.S.
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No. 86-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

DAIG CORPORATION,

Petitioner,

vs.

MEDTRONIC, INC., and
MEDTRONIC PUERTO RICO, INC.,

Respondents.

EXHIBITS SUPPLEMENT

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United States Patent [19]

Citron et al.

[11] **3,902,501**

[45] **Sept. 2, 1975**

[54] **ENDOCARDIAL ELECTRODE**

[75] Inventors: **Paul Citron**, New Brighton; **Eugene A. Dickhudt**, St. Paul, both of Minn.

[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[22] Filed: **June 21, 1973**

[21] Appl. No.: **372,269**

[52] U.S. Cl. ..... **128/418**; 128/404; 128/419 P

[51] Int. Cl. **A61n 1/04**

[58] Field of Search.... 128/418, 419 P, 404, 2.05 F, 128/407–409, 242–244, 325, 344, 345, 348–350, DIG. 16, 2.06 E

[56] **References Cited**

UNITED STATES PATENTS

2,854,983	10/1958	Baskin	128/349 B
3,348,548	10/1967	Chardack	128/419 P
3,397,699	8/1968	Kohl	128/243
3,516,410	6/1970	Hakim	128/350 R
3,568,659	3/1971	Karnegis	128/243
3,608,555	9/1971	Greyson	128/348
3,717,151	2/1973	Collett	128/350 R
3,719,190	3/1973	Avery	128/418
3,815,608	6/1974	Spinosa et al.	128/349 R
3,835,864	9/1974	Rasor et al.	128/418 X

OTHER PUBLICATIONS

Schaldach, "New Pacemaker Electrodes," Trans: Am. Society For Artificial Internal Organs, Vol. 17, 1971, pp. 29–35.

Wende et al., "Neve intrakardicle Schrittmacherelektrode," Deutsche Medizinische Wochenschrift, Nr. 40, 2, Oct. 1970, pp. 2026–2028.

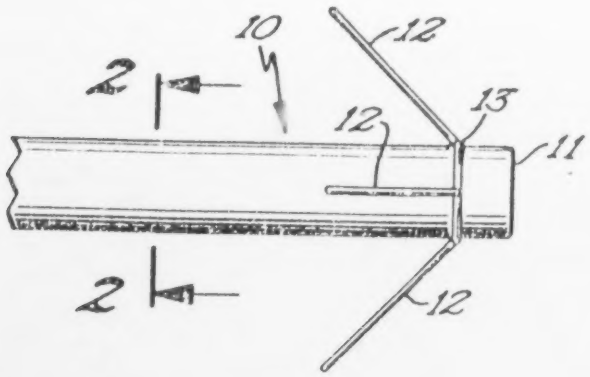
Pieper, "Registration of Phesic Changes of Blood Flow by Means of Catheter Type Flowmeter," Review of Sci. Instr., Vol. 29, No. 11, Nov. 1958, pp. 965–967.

Primary Examiner—Richard A. Gaudet
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[57] **ABSTRACT**

A medical electrode uniquely adapted for use as an endocardial electrode. An electrical conductor is encased in a material which is generally inert to body fluids and terminates at an exposed electrically conductive tip. A plurality of pliant tines extend from the electrode adjacent the tip and form an acute angle with the electrode body. Provision is made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position. The released tines cooperate with the heart tissue, particularly the trabeculae found in the ventricles and the right atrial appendage, to maintain the electrode tip in position.

17 Claims, 13 Drawing Figures



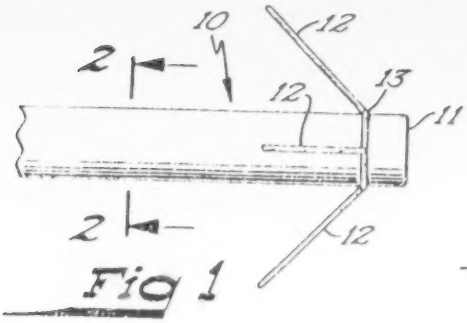


Fig 1

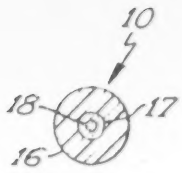


Fig 3

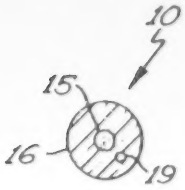


Fig 2

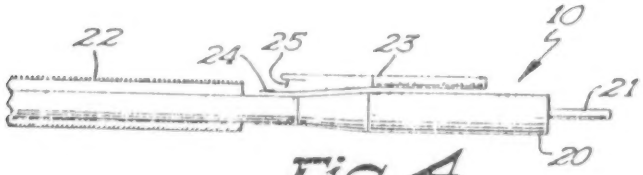


Fig 4



Fig 5

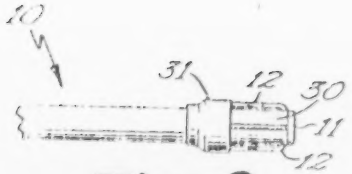


Fig 6

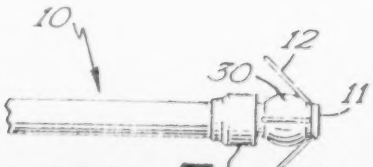


Fig 7

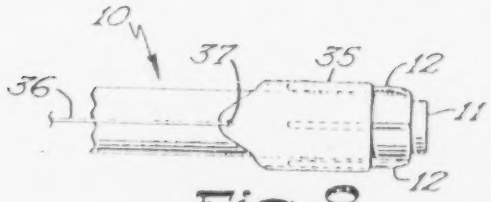


Fig 8

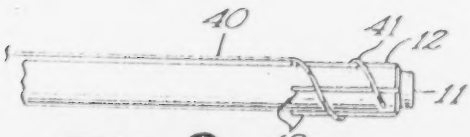


Fig 9

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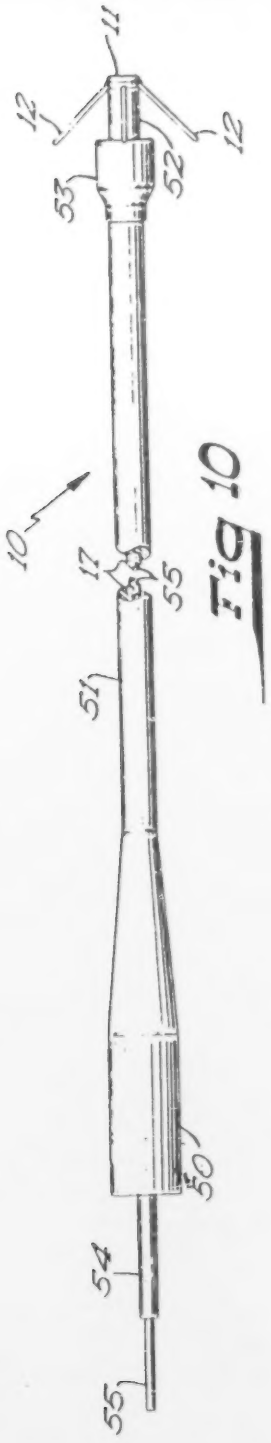


Fig 10

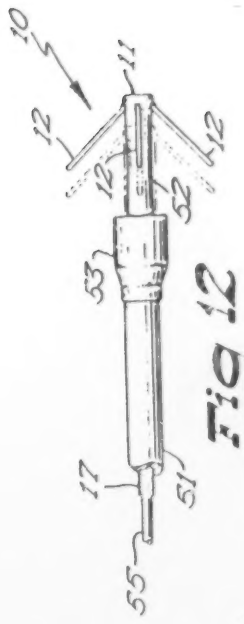


Fig 12

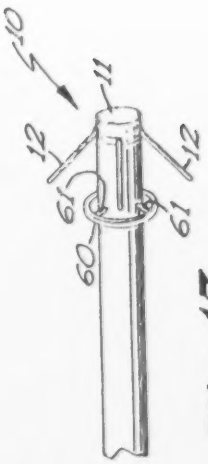


Fig 13

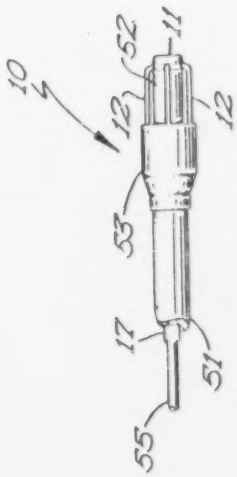


Fig 11

ENDOCARDIAL ELECTRODE

BACKGROUND OF THE INVENTION

Electrical stimulation of heart action is well-known and has been employed to counter a variety of heart dysfunctions. Dependent upon the particular dysfunction, optimal placement of the electrical contact point or points may vary. However, optimal electrode placement has often been sacrificed to other considerations such as minimization of the surgical risk and reliability of the electrode securement. To date, the greatest number of electrodes have been ventricular electrodes with the transvenous-endocardial approach coming into the fore in recent years.

The advantages of a reliable electrical contact with the atrium are well-known. Such a contact would allow atrial pacing or atrial synchronized pacing thereby preserving the contribution of the atrial contraction in the overall cardiac output. Additionally, an atrial contact would be advantageously employed for arrhythmia management and other purposes which may not be accomplished through ventricular electrical stimulation. For reasons well-known to those skilled in the art, the greatest advantages can be obtained through an electrical contact with the right atrium, the right atrial appendage providing a suitable site.

An attempt to accomplish transvenous or endocardial atrial pacing is described in Smyth et al. "Permanent Transvenous Atrial Pacing, An Experimental and Clinical Study", The Annals of Thoracic Surgery, Volume 11, No. 4, Apr. 19, 1971, pages 360–70. Here, a J-shaped catheter with a flange near the tip was inserted into the right atrial appendage through a transvenous approach. The catheter was straightened by the insertion of a stylet. When the stylet was withdrawn, the catheter assumed its preformed J shape for placement of the electrode tip in the atrial appendage. There was no attempt to artificially secure the electrode tip in position, the atrial trabeculae and shape of the catheter being relied upon to maintain it in location until the heart tissue itself enveloped and fixed the tip. The metal parts of the catheter may be radiopaque to facilitate placement by viewing through fluoroscopy.

A sensing atrial endocardial electrode is described in Portsmann et al., "P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy", The American Journal of Cardiology, Volume 30, July 11, 1972, pages 74–76. A J-shaped applicator catheter was used to direct the electrode tip into the right atrial appendage. The electrode however, had two fine wire hooks positioned at its tip each ending in a relieving loop. The hooks were held back by the applicator catheter to spring out and anchor the electrode in the trabeculae of the right atrial appendage when the electrode tip left the end of the applicator catheter.

In the applicator catheter technique described above, the applicator catheter was radiopaque so that it could be viewed as it was inserted into the right atrial appendage. It is imperative with the double hook tip that the electrode be properly placed before the hooks are released. The placement was checked not only through fluoroscopy but also by extending the tip slightly beyond the end of the applicator catheter to take a threshold measurement. The tip had to be extended sufficiently to take an accurate measurement while still retaining the hooks within the applicator catheter. Because of its size, it is extremely difficult to accomplish this test measurement without also releasing the hooks. Additionally, the metallic nature of the hooks, their sharp points and spring action creates the possibility that the hooks may perforate the wall of the appendage if the catheter tip is not precisely positioned. Also, the configuration and rigidity of the hooks make it extremely difficult to remove the electrode without damage to the heart tissue while its metallic properties severely limit its utility as a pacing electrode.

SUMMARY OF THE PRESENT INVENTION

The present invention provides an electrode uniquely adapted for use as an atrial endocardial electrode. The electrode may be positioned in the right atrial appendage through the use of a J-shaped catheter known to the prior art. Alternatively, a J-shaped stylet may be employed which is held in a straightened position by the walls of the vein used to approach the heart, the stylet assuming its J-shape upon entry into the right atrium. A plurality of pliant non-conductive tines are provided at the tip of the electrode to cooperate with the heart tissue, particularly the trabeculae found in the right atrial appendage, to maintain the electrode tip in electrical contact with the heart tissue while allowing a removal of the electrode should that prove necessary. Provision is also made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position and after a test threshold measurement. Although the electrode is discussed in the context of the right atrial appendage, it is suitable for use in any portion of the heart having the requisite cooperating tissue and may be employed as either a sensing or pacing electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a preferred embodiment of the present invention.

FIG. 2 shows a cross section of the preferred embodiment of FIG. 1 taken along the line 2—2 in FIG. 1.

FIG. 3 shows a cross section of another preferred embodiment taken along the line 2—2 in FIG. 1.

FIG. 4 illustrates apparatus which may be used with the preferred embodiment of FIG. 1.

FIG. 5 shows a component of another preferred embodiment of the present invention.

FIG. 6 shows a preferred embodiment of the present invention which utilizes the component of FIG. 5, the tines being in a restrained position.

FIG. 7 shows the embodiment of FIG. 6 with the tines unrestrained.

FIG. 8 shows another preferred embodiment of the present invention.

FIG. 9 shows still another preferred embodiment of the present invention.

FIG. 10 shows a further preferred embodiment of the present invention.

FIG. 11 shows a portion of the preferred embodiment of FIG. 10.

FIG. 12 shows a portion of the preferred embodiment of FIG. 10.

FIG. 13 shows an additional preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring now to FIG. 1, there is shown a body member 10 terminating at an exposed electrically conduc-

tive tip 11 and a plurality of tines 12 extending at an acute angle from the body member 10 from a position adjacent the tip 11. The electrically conductive tip 11 may be of any material suitable for the environment; platinum-iridium, for example. The tines 12 are of a pliant material which is generally inert to body fluids; silicone rubber or polyurethane, for example. The tines 12 may be attached to the body member 10 in any convenient manner. For example, the tines may extend from, and be unitary with, a disc 13 which disc is held in position between the body member 10 and tip 11. Alternatively, the member 13 may be in the form of a ring which lies over either the body member 10 or tip 11 and is adhered thereto in any convenient manner. The tines 12 may take any angle with the body member 10, their purpose being to cooperate with the body tissue, particularly the trabeculae of the right atrial appendage, to maintain the tip 11 in electrical contact with the body tissue. It can be seen that an acute angle formed by the tines 12 and the body member 10 will have the greatest tendency to push against and become involved with the cooperating trabeculae and maintain the tip 11 in electrical contact. It has been found, that an angle of approximately 45° maintains the necessary electrical contact is a very efficient manner. Further, any number of tines may be used, three having proven to be adequate in most situations.

Referring now to FIG. 2 wherein there is shown a cross section of a preferred embodiment of the body member 10 of FIG. 1 taken along the line 2—2. In this embodiment, an elongated electrical conductor 15 runs substantially the length of the body member 10 and makes electrical contact with the tip 11. The conductor 15 is encased within a catheter 16 of a material which is generally inert to body fluids.

It is desirable that the catheter — conductor combination be made as flexible as possible. To accomplish this purpose while providing the necessary rigidity for insertion of the electrode, a stylet lumen 19 is provided, the stylet being within the lumen 19 during insertion of the electrode and being withdrawn after placement is accomplished. In a preferred embodiment, the stylet which is placed into the lumen 19 has a J configuration similar to that of the prior art applicator catheters. During insertion, the stylet is maintained in a "straightened" configuration by the walls of the vessel through which insertion is accomplished. When the electrode tip reaches the atrium, the stylet assumes its J configuration thereby allowing an easy insertion into the appendage. When the placement of the electrode tip is accomplished, the stylet is withdrawn. In this embodiment, the electrical conductor can be of any known type, one preferred form being a multistrand wire of platinum, for example, commonly referred to as "tinsel wire."

A second preferred form for the body member 10 is illustrated in FIG. 3. Here, the electrical conductor is a coiled member 17 which again runs substantially the length of the body member 10. The coil 17 is encased in a catheter 16 substantially identical to that shown in FIG. 2. The central portion of the coil 17 is left at least partially void to form a lumen 18 for the insertion of a stylet, the stylet serving essentially the same function in this embodiment as in the embodiment of FIG. 2. Further, in both the embodiments of FIG. 2 and FIG. 3, the lumens 19 and 18 may be lined with Teflon or any other appropriate material to facilitate the insertion and removal of the stylet.

Referring now to FIG. 4, there is again shown an electrode body portion 10 this time at the end farthest from the tip 11. In some applications, a pin type connection to an external stimulator or sensing device is desired. For this purpose, the body portion 10 commonly has an enlarged segment 20 from which extends the connecting pin 21. If it is desired to insert the electrode through the use of the J-shaped applicator catheter known to the prior art, the catheter must be made sufficiently large to slide back over the enlarged portion 20 or, alternatively, some other system for removal of the catheter must be provided. Here, the applicator catheter is shown at 22 of a size not sufficiently large to be withdrawn over the enlarged portion 20. A cutting tool 23 is shown adjacent the enlarged portion 20 and extending forward of the enlarged portion with a wedge 24 and a knife blade 25. The cutting tool 23 may be separate from the electrode body 10 or may be attached thereto in any convenient manner. In operation, the wedge portion 24 slips under the edge of the applicator catheter 22 and, as the applicator catheter 22 is drawn toward the cutting tool 23, the wedge will direct the catheter 22 into contact with the knife blade which will then cut and separate it thus allowing the removal of the applicator catheter over the enlarged portion 20.

The electrode shown in the embodiment of FIG. 1 may be successfully inserted into the right atrial appendage through a transvenous approach using the stylet technique of either FIGS. 2 or 3 or the J-shaped applicator catheter technique. In the applicator catheter technique, the tines 12 are not exposed during insertion. In the stylet technique of either FIGS. 2 or 3, however, the tines are non-restrained or extended during the entire operation. Although the electrode may be successfully positioned in this condition, it is found that the blood flow tends to draw the electrode tip into the ventrical. For this reason, some means of restraining the tines during insertion is desirable.

Referring now to FIG. 5, there is shown a balloon catheter similar to the balloon catheters used for other applications. Specifically, the catheter body 10 has a portion 30 which is inflatable from an end 32. The inflation is accomplished through a lumen similar to the stylet lumen 19 and 18 of FIGS. 2 and 3 respectively. Indeed, the inflation can be accomplished through the stylet lumens 19 and 18, the lumens being made sufficiently large to accomodate the stylet while allowing a passage for air to inflate the balloon. The ballooning feature of the electrode body 10 may be accomplished in any known manner. Referring now to FIG. 6, there is shown an electrode having a body 10 and a tip 11 as described with reference to the embodiment of FIG. 1. The body 10 is composed of a balloon catheter as illustrated in FIG. 5 with the ballooning or inflatable part lying adjacent the tip 11. A hold down shroud 31 is positioned near the tip 11 and is adapted to receive at least the ends of the tines 12 to restrain them in a position wherein they overlie the inflatable portion 30 of the electrode body 10. With the tines in this restrained position, a stylet may be inserted into a lumen such as that illustrated in FIGS. 2 or 3 and the electrode inserted through a transvenous approach without any interference from the extended tines. When the electrode tip is believed to be in an acceptable position as viewed by fluoroscopy, a test measurement can be made. If the

site of the electrode tip proves satisfactory, the balloon 30 can be inflated from the end of the electrode still outside the body causing the tines to withdraw from the shroud 31 and extend into their normal unrestrained position as illustrated in FIG. 7. With the tines freed from the shroud 31 the inflating pressure can be released and the balloon 30 will deflate to a normal configuration. The shroud 31 may take any shape which can accept at least the end portions of the tines 12. A ring which is attached to the body by spaced tethers is an example of an obvious modification of the shroud 31.

An alternative shroud to the shroud 31 of FIG. 7 is illustrated at 35 in FIG. 8. This shroud 35 again is adapted to accept at least the end portion of the tines 12 to restrain them in a position wherein they overlie the body of the electrode 10. A line 36 is attached to the shroud 35 at 37, and when the tip is properly positioned, a force on the line 36 will cause the shroud 35 to withdraw thus freeing the tines 12 to assume their extended unrestrained position. A similar approach is illustrated in FIG. 9 wherein a stylet 40 is shown having a coiled portion 41 which coiled portion is wrapped around the tines causing them to lie flat against the body member 10. Again, when the tip 11 is properly positioned, the stylet will be withdrawn thereby freeing the tines for interaction with the trabeculae of the right atrial appendage, for example.

Referring now to FIG. 10, there is shown another preferred embodiment of the present invention. Specifically, there is shown an electrode body 10 composed of a connecting portion 50, a central portion 51 and an end portion 52 which lies between the tip 11 and the shroud 53. The cross section of the central portion 51 may be as illustrated in FIG. 3. That is, the electrical conductor is a coiled member 17 having a void lumen forming central portion 18, the conductor extending from the tip 11 back to the connecting portion 50. The connecting portion 50 is similar to that illustrated in FIG. 4 with the connecting pin 54 making an electrical contact with the electrical conductor 17 and having a lumen coincident with the lumen 18 of the conductor 17. With this configuration, it is possible to insert a stylet 55 through the end of the connecting pin 54 to abut the tip 11. Inasmuch as the electrical conductor is a coiled member it can be stretched or elongated by applying a pressure against the tip 11 with the stylet 55. Since the electrical conductor is typically uniform throughout its length, the location at which the electrode body will give or elongate can be controlled to the durometer or diameter of the electrode body, or both. For reasons to be explained more fully below, it is desired that the portion 52 of the electrode body 10 "give" before the central portion 51 or the connecting portion 50. Therefore, the portion 52 is illustrated as having a smaller diameter than either the central portion 51 or the connecting portion 50. Alternatively, the material comprising the portion 52 may have a lower durometer than either of the other portions of the electrode body 10 or it may have a lower durometer and diameter as desired.

FIG. 11 illustrates the embodiment of FIG. 10 with the tines 12 having at least their ends restrained by the shroud 53 in a manner substantially identical to that illustrated in FIG. 6. With the tines in their restrained position, the electrode can be inserted and positioned and when a proper positioning is obtained as described above, the stylet is forced against the tip 11 causing the portion 52 to stretch as illustrated in FIG. 12 thereby releasing the tines 12 from the shroud 53. With the tines released, the stylet is removed thereby allowing the portion 52 to assume its normal shape as illustrated in phantom at FIG. 12.

As stated with regard to the shroud 31 of FIGS. 6 and 7, the shroud 53 of FIGS. 10-12 may take the form of a ring connected to the electrode body by means of a plurality of tethers. Such a ring shroud is illustrated at 60 in FIG. 13. As can be seen, the shroud 60 has a ring or a "doughnut" configuration and is held in place by means of tethers 61 which perform essentially as the spokes of a wheel, the tethers 61 being positioned so as not to interfere with the restraining and release of the tines 12.

From the above, it can be seen that the present invention provides a new medical electrode uniquely adapted for use as an endocardial electrode. The electrode provides means for cooperating with the heart tissue, particularly the trabeculae of the ventricles and right atrial appendage, to provide an artificial fixation until such time as a natural fixation has occurred. The tines are of a pliant material which is sufficiently rigid to accomplish their purpose without having the snapping action and sharp points attendant in the prior art devices. Further, the present invention provides a system for positioning the electrode and making any necessary test measurements prior to its being finally positioned, the position of the tip with regard to the inserting devices being much less critical in the present invention than in the prior art devices because the tines may be selectively released independently of the insertion device.

Obviously, many modifications and variations of the present invention are possible in light of the above teaching. An example of such a modification would be to make the body member 10 or the tines 12, or both, radiopaque to facilitate the positioning by observation of the electrode through X-ray, fluoroscopy, etc. We have found that this can be accomplished through impregnation with carbon, barium sulfate or Tantalum. Of course, any suitable substance and method will be acceptable for this purpose. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

2. The lead of claim 1 wherein the improvement further comprises means external to said encasing mate-

rial for releasably restraining said tine means in a position overlying said encasing material.

3. The lead of claim 2 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

4. The lead of claim 3 wherein said restraining means further comprise means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

5. The lead of claim 3 wherein the improvement further comprises:

inflatable means underlying said tine means when said tine means are in said restrained position; and

means spaced from said inflatable means for selectively inflating said inflatable means.

6. The lead of claim 4 wherein said tine means are non-metallic.

7. An endocardial lead which comprises:

elongated electrically conductive means;

flexible catheter means surrounding said electrically conductive means and having a lumen substantially parallel to and coextensive with said electrically conductive means;

electrically conductive tip means at one end of said catheter means and electrically connected to said electrically conductive means; and

nonconducting tine means extending from said catheter means and away from said tip from a point adjacent said tip means for cooperation with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said catheter means and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

8. The lead of claim 7 further comprising means for releasable restraining said tines in a position wherein they overlie said catheter means.

9. The lead of claim 8 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

10. The lead of claim 9 wherein said restraining means further comprises means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

11. The lead of claim 9 wherein said catheter means comprises a balloon catheter, the balloon underlying the tines when the tines are in the restrained position.

12. The lead of claim 11 wherein said elongated electrically conductive means comprises a coiled electrical conductor having a void central portion, said lumen coinciding with said void central portion.

13. The lead of claim 11 wherein said elongated electrically conductive means is positioned substantially at the center of the cross section of said catheter means and said lumen lies off the center of said cross section.

14. In a medical lead of the type in which an electrical conductor is positioned within a catheter and terminates at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means including a plurality of tines each extending from said catheter and away from said tip from a point adjacent said tip and forming an acute angle with said catheter for cooperating with heart tissue to hold the tip in position, said tine means being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue;

means for releasably restraining said tine means in a position wherein said tine means overlie said catheter; and

means underlying said tine means when said tine means are in said restrained position and inflatable from a point spaced from said restraining means for releasing said tine means from said restraining means upon inflation.

15. The medical lead of claim 14 wherein the angle formed by said tine means and said catheter is approximately 45°.

16. The medical lead of claim 14 wherein said pliant tine means material comprises a material which is relatively inert to body fluids, at least a portion of said material being radiopaque.

17. The medical lead of claim 16 wherein the radiopaque material portion is a material treated with a material selected from the group consisting of carbon, barium sulfate or Tantalum.

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Rasor et al.

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[45] Sept. 17, 1974

[54] INT A-CARDIAC STIMULATOR

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[51] Int. Cl. A61n 1/36
[58] Field of Search ..... 128/404, 418, 419 P, 421, 128/422

[56] References Cited

UNITED STATES PATENTS

3,087,486	4/1963	Kilpatrick	128/404
3,516,412	5/1970	Ackerman	128/418

FOREIGN PATENTS OR APPLICATIONS

246,004	11/1969	U S S R.	128/419 P

OTHER PUBLICATIONS

Hopps et al., "Surgery," Vol. 36, No. 4, Oct., 1954, pp. 833-849 (only p. 834 relied on).

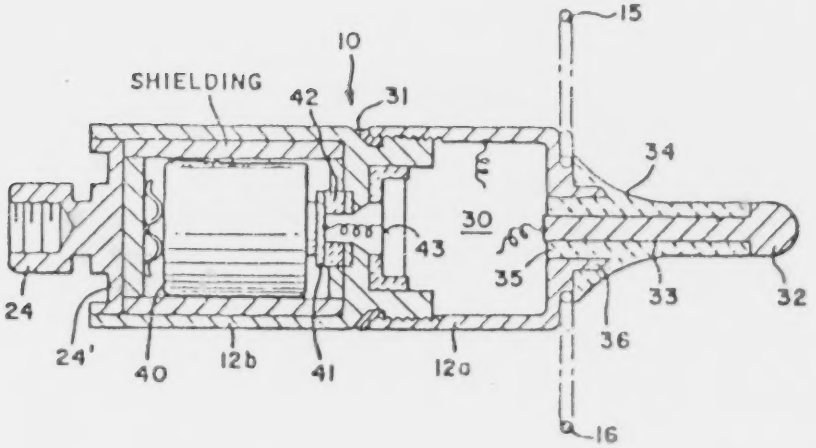
Frei et al. "Medical Research Engineering," 4th Quarter, 1956, pp. 11-18.

Primary Examiner—William E. Kamm

[57] ABSTRACT

A stimulator device for insertion in a living body and having particular advantage for intra-cardiac use comprising a structure having a body form of a size and configuration to enable its transvenous or transarterial insertion, the surface of said body form providing electrode means for contact with a portion of the living body to be stimulated by said electrode means, and means mounted to project outwardly of and peripherally of said body form including anchor portions locating in a position displaced from said electrode means and providing means for engaging in portions of said living body to establish said electrode means in a required position of use, said electrode means having in connection therewith means to energize the same once said body form is located in its required position of use.

7 Claims, 14 Drawing Figures



INTRA-CARDIAC STIMULATOR

BACKGROUND OF THE INVENTION

Implanted Pacemaker devices are now commonly employed for the long-term treatment of atrio-ventricular (A-V) block. Such Pacemaker devices commonly employ flexible leads which connect a remotely positioned power pack with electrodes which are placed in contact with or attached to the myocardium. The techniques of implanting and using such Pacemakers, and many Pacemaker which have been used experimentally and in practice, are described by Siddons and Sowton, *Cardiac Pacemakers* (1967), published by Charles C. Thomas, Springfield, Illinois, Library of Congress Card No. 67-12042. Pacemakers having energy sources responsive to heart movement are shown in U.S. Pat. Nos. 3,358,690 and 3,486,506.

Such Pacemakers, or other biological stimulators working on these principles, have inherently suffered from certain disadvantages. The leads to the electrodes are commonly routed through veins leading into the heart itself. The movement of the heart and normal activity of the individual tend to put a strain on these leads and may result in lead breakage or dislodgement of the electrodes. The leads themselves, retained in situ, are frequently a source of irritation and infection. Further, since the electrical contact with the heart is made at the point or region of mechanical support or implantation, the normal fibrosis of tissue at these regions often results in a marked increase power required to pace, known as an increase in threshold. For example, the threshold has been found to increase on the order of ten times its original value until a plateau is reached over a period of two to three weeks. This requires a correspondingly greater power input to the electrodes, in the minimum of 3:1 over threshold, in order to achieve consistent pacing.

The remote power pack itself is a cause of discomfort and often a cause of difficulty. It is commonly implanted in a subcutaneous pocket beneath the pectoralis major or within the abdomen. Again, this provides a further opportunity for infection. Difficulty has been encountered in preventing migration of the power pack. Further, surgery is required from time to time to expose and replace the power pack due to exhaustion of the mercury cells. Prior pacing devices which derive their energy from the heart movement or pressures have commonly required thoracic surgery for attachment to the epicardium, and have employed flexible leads to the electrodes.

SUMMARY OF THE INVENTION

The present invention is directed to a wholly selfcontained stimulator which is particularly adapted for use as a Pacemaker. It is contained within a package or housing which is sufficiently small to be implanted by catheter insertion (transvenous or transarterial) into a chamber of the heart where it is attached to the endocardium. The stimulating electrodes are formed integrally with the unit, without external leads, and thus make contact with the endocardium. As used herein, "catheter" refers to an inserting device embodying a sheath-like element of small bore tube form.

A Pacemaker device made according to the present invention is intended primarily for long-term use. It can be used without discomfort to the user. The likelihood of a failure due to dislodgement of electrode contact, increase of threshold, or occurrence of infection is substantially reduced. Failure due to electrode lead breakage is eliminated entirely. The device can be implanted by a catheter device and technique which require only minor surgery and temporary discomfort to the patient. It can be recovered if desired or, if failure should occur it may simply be left in place and a new device inserted.

In one form of the invention a nucleonic battery is employed for providing a power source to the pulse generator circuits contained within the housing. This arrangement provides for an overall life which may be well beyond the normal life expectancy of the patient. For example, Pu-238 has a half life of 86 years, while Pm-147, which may be preferred because of lower costs, has a half life of 2.7 years. Suitable electronics in the converting and pulse generating portion are available which operate efficiently over three or more half lives. Operation over such a large power range is made possible in part by the fact that the device of the present invention does not cause a material or significant increase in threshold, and therefore can continue to operate after decay to very low power levels.

Three forms of the invention are disclosed which employ a biologically energized power source and thus derive their power requirements from the body itself. Prior attempts have obtained insufficient power from normal heart activity to provide reliable and continuous pacing. However, the apparatus of the present invention is one which does not result in a significant increase in threshold power and accordingly reliable pacing may be affected over an extended period of time with modest lower power requirements. The energy required for each stimulation pulse may be in the order of one microjoule or less, corresponding to a total power input to the electronics on the order of six microwatts or less. The mechanical work which is available substantially exceeds this.

In one form of the invention, a movable wall or diaphragm transforms hemodynamic pressure into electric energy by means of a suitable transducer. In other forms of the invention, a mass is suspended in such a manner that movements of the heart set up a sympathetic or harmonic movement of the mass, and this movement may be electromechanically coupled to produce energy. For example, the transducer may comprise a permanent magnet in combination with a non-moving electric coil. In another form, the mass may be connected to stress a piezoelectric crystal.

The body or housing structure of the present invention may also be used as the electrode structure for existing Pacemakers, as it offers certain advantages over the endocardial electrodes which are presently in use.

Another important object of the invention is the provision of a bioelectric stimulator which is fully self-contained and implantable at the site of stimulation, and an improved electrode structure therefor.

A further object of the invention is the provision of a stimulator, heart Pacemaker, or an electrode structure for a Pacemaker, in which the region of attachment is spaced from the region of stimulation to avoid the adverse effects of tissue fibrosis at the region of attachment.

A further object of the invention is a provision of a catheter for inserting the Pacemaker or electrode as-

sembly therefor, as described above, and the further provision of the combination of a novel catheter and Pacemaker or electrode assembly therefor. The catheter is preferably a triaxial arrangement in which one of three concentric elements is removably secured to the body of the device, a second element forms a torque tube which may be used to assist in implanting the device and for removing the first element from the device, and the third element comprises an outer removable sheath which preferably extends at least partially over the body of the device during transvascular passage and may be employed to retain the body-attaching members on the device in a retracting or inoperative position until the device has been positioned, as desired. Thereafter, the sheath may be retracted to expose the body of tissue-attaching members, or extended to cover these members for removal of the device from the heart.

These and other objects and advantages of the invention will be apparent from the following description, the accompanying drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of the stimulator and catheter devices of the invention;

FIG. 2 shows parts of FIG. 1 in an assembled condition;

FIG. 3 is an enlarged sectional view, partially in diagrammatic form, of the stimulator of FIG. 1 adapted particularly for use as a heart pacer;

FIG. 4 is an end view of the device of FIG. 3;

FIGS. 5*a*, 5*b* and 5*c* are, respectively, diagrams illustrating the method of implanting the pacer using the catheter device of this invention;

FIG. 6 is a schematic drawing showing a pulsing circuit which may be used with this invention;

FIG. 7 is a diagram of a modified form of the circuit of FIG. 6 particularly adapted for use with a nucleonic or other varying power source;

FIG. 8 shows a modified form of the invention adapted to respond to hemodynamic pressure changes;

FIG. 9 is a block diagram of the pacer of FIG. 8;

FIG. 10 is a further modification showing a biologically powered pacer according to the present invention;

FIG. 11 is a still further modification showing another form of the biologically powered pacer; and

FIG. 12 is a modified catheter and an improved Pacemaker electrode assembly according to the teachings of this invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIGS. 1–4, a self-contained stimulator 10, particularly is adapted as a heart pacer, and a catheter 11 is adapted for use with such pacer. The pacer 10 is formed with an elongated capsule-like, generally cylindrical body 12. Preferably, the body 12 is formed exclusively on its outer surfaces of biologically compatable materials, the major portion of which may be stainless steel. While the outer surface of the body 12 is shown in the drawings as being formed essentially of smooth inert material, such as stainless steel, it is within the scope of this invention to provide the body with a compatible flocking material, such as a dacron weave to promote the formation of neointima once the unit has been implanted.

The device can be implanted in any of the four chambers of the heart where patho-physiology would be optimum for a particular patient. However, the preferred embodiment herein will emphasize implantation within the right ventricle where the greatest clinical and experimental experience has been concentrated to date. When the stimulator, or pacer 10, is adapted for implantation directly within a heart ventricle, it should have a maximum overall length not substantially exceeding 30mm and preferably in the order of 18mm or less. The diameter of the body 12 should not substantially exceed 10mm and is preferably 8mm or less. Such dimensions provide a self-contained Pacemaker which is sufficiently small to permit catheter transvascular insertion into a ventricle, and permit it to be received within such ventricle without disturbing the proper function of the heart.

The forward end of the body 12 is provided with means for attaching the pacer 10 to the myocardium. A preferred form of the attachment comprises a pair of oppositely directed spiral stainless steel attaching points or wires 15 and 16, as best shown in FIG. 4. The wires have inner ends attached to the circumference of the body 12 and free outer ends. These attaching wires are adapted to be retained in a retracted position in closely surrounding relation to the circumference of the body 12, but when released, spring out to the expanded or operative position, as shown.

Catheter means for transvenous implanting of the Pacemaker 10 preferably consists of the triaxial device illustrated generally at 11 in FIGS. 1 and 2. This arrangement comprises a central rod 22 which is formed with a threaded end 23 which is adapted to be attached or received with a suitable internally threaded nut 24 formed on the rear wall 24' of the body 12, as shown in FIG. 3. A torque tube 25 is slidably received over the rod 22 and, at its forward end, is formed with an internal socket portion 26 adapted to be received over the nut 24 in driving engagement with the Pacemaker 10. The catheter is further provided with an axially slidable sheath 27 which has a forward metallic end portion 28 of a diameter sufficiently to be received at least partially over the body of the Pacemaker 10. In use, the sleeve 28 substantially covers the Pacemaker and retains the attaching wires 15 and 16 in their retracted position substantially as shown in FIG. 2. The use of the catheter 11 is further described in connection with the illustration of FIGS. 5*a–c*.

This entire catheter system may be rigid with defined bends or may be flexible or may be steerable. In the preferred form, a central rod 22 and the torque tube 25 are flexible, while the forward end of the sheath 27 is formed with a predetermined bend as indicated at 27' in FIG. 5*a*. The bend which may be formed within 2–4 inches of the end of the catheter assembly, may have an angle of approximately 30° in order to permit the catheter and the attached Pacemaker to be steerable around corners and bends.

Referring particularly to FIG. 3, the Pacemaker 10 is shown as including a forward body portion 12*a* and a cylindrically continuous rear body portion 12*b*. The forward portion 12*a* is hollow and contains the electronic pulsing circuit 30, illustrative examples of which are shown in FIGS. 6 and 7. It has been found that relatively simple circuits are totally satisfactory and are in

fact preferred over the more complicated circuits shown, for example, in the reference text referred to under the Background section of the specification. The simpler circuits generally have lower losses and greater overall reliability. Such circuits can easily be fitted within the activity defined with the body section 12*a* without the necessity of reverting to microminiature or integrated circuits. However, such circuits permit even further miniaturization, but the overall size of the stimulator of this invention is dictated not so much by the circuit requirements but by the space requirements of the power source.

The body sections 12*a* and 12*b* may be threaded together and sealed as shown at 31, but it is within the scope of this invention to make the body 12 of simple one-piece construction. The rear wall 24' is preferred welded to the case 12*b* by electron beam welding. There is some advantage in the two-piece body construction of FIG. 3 in that it permits the body parts to be separated and adjustments to be made to the circuit prior to insertion.

One of the important advantages of the stimulator of the present invention resides in the fact that the pacing electrodes are formed integrally with outer surfaces of the body 12. To this end, the body portions 12*a* and 12*b* themselves define the positive pulsing electrode which, as previously noted, may be formed preferably of stainless steel. The negative pulsing electrode 32 is formed preferably of platinum and supported on a forwardly extending dielectric pedestal 33. The pedestal is preferably formed of an inert ceramic, defining a hollow co-axial insulator. The insulator 33 may thus have an outer curved surface 34 leading smoothly from the electrode end 32 and flaring outwardly at the body 12*a* to assist in guiding the device during insertion. A tubular portion 35 extends into the interior of the body 12*a*. The forward end of the body 12*a* is formed with an annular ledge 36 to provide support for the insulator and for the electrode 32.

The stimulating electrode 32 may also be of the differential current density type, known as the "Parsonnet Electrode" and described by George H. Myers and Victor Parsonnet in *Engineering in the Heart and Blood Vessels*, (1969) John Wiley & Sons, New York, N.Y.

The arrangement as shown has several important advantages. In the first place, it will be noted that, unlike prior devices, the electrodes do not themselves form or comprise the attaching devices. Rather, the pacing electrodes are well spaced axially from the barbs 15 and 16. Thus, once these electrodes have made reliable pacing contact with the heart tissue, they do not transmit the destructive forces of attachment and retention to this tissue, and they remain free of the adverse affects of fibrosis which invariably occurs at the regions of attachment or forcible retention. In devices where the electrodes themselves are directly attached or are forcibly retained by pressing against the tissue, an approximately 10 times increase in the threshold is not uncommon. This occurs over approximately a two to three week period subsequent to implanting and then reaches a plateau. Such a substantial increase in threshold requires a corresponding increase in power requirements simply to overcome the threshold and to effect reliable stimulation. The elimination of the cause of threshold rise permits reliable pacing with substantially lower power consumption.

Another important advantage of the construction of FIG. 3 is the total elimination of external flexible leads between the pacing circuit and the tissue to be stimulated. This then results in the elimination of the lead placement and breakage difficulties which are inherently associated with remotely positioned pacer circuit.

A further important advantage of the pacer of this invention is the fact that it can be reliably powered from a suitable nucleonic power source 40. There are available in the present state of the art a number of nucleonic conversion devices which may be contained within the physical dimensions of the body portion 12*b*, and suitably shielded and sealed therein. A preferred form of such device is a betavoltaic converter which is, in effect, a stack of semiconductor photocells which are coated with a radioactive material and which are irradiated by beta particles to produce an unidirectional current electric output. Beta sources may include Pm-147 which has a 2.7 years half life. It is within the state of the art to provide an electronic circuit which will operate effectively over more than three half-lives of such power sources within the volume available. The use of tritium, with a half life of 12.6 years, is also possible.

A power source 40 using radioisotope fuel may also be of the thermionic type, the thermoelectric type or the double conversion type. In the thermionic and thermoelectric types, heat from the radioisotopic fuel is transformed into electric power by electron transport through a thermionic diode or thermocouple respectively. In the double conversion type, radiation from the radiosotope fuel is employed to excite a light-emitting phosphor, and the photons in turn excite a semiconductor photocell. All three of these types can use Pu-238, which is a desirable fuel for biological applications and has a half life of 86 years. The choice of fuel and type of convertor will depend upon the cost of the source material and fabrication, the half life, and the efficiency of conversion as well as the shielding required. Suitable radioisotope-fueled batteries are made by Donald W. Douglas Laboratories, 2955 George Washington Way, Richland, Washington and sold under the tradenames "Betacel" and "Isomite," representing beta-voltaic and thermionic types respectively. While nucleonic power sources are preferred by reason of long life, it is within the scope of the invention to employ rechargeable batteries, or mercury cells. The latter may be satisfactory for short term pacing, in view of the relatively high overall efficiency of the device.

As shown in FIG. 3, an insulated plate 41 in contact with the power source is hermetically sealed by an insulator 42, and leads 43 extend to the circuit contained within the body section 12*a*. The case 12 is negative with respect to the power source but is positive with respect to the biological load.

The diagram of FIG. 6 illustrates one form of the pulsing circuit in which a power source 40 is shown as providing an output voltage of approximately 39 volts. This output is applied through charging resistor 44 and through the load 45 to a capacitor 46. The time required to charge the capacitor will depend upon the charging time constant of the circuit, and since the biological load 45 is normally less than 1,000 ohms it forms a small part of the total resistance in the charging circuit. However, as long as the load 45 is present the circuit will charge.

The transistors 48 and 49 comprise a transistor switch. This switch automatically becomes conductive to connect one side of the capacitor 46 to ground at some predetermined potential during the charging of the capacitor 46, and thus provides a low impedence grounding circuit permitting a discharge of the capacitor through the load 45. The peak load voltage may be 1.3 volts, and the transistor switch may be conductive for 3ms. Thereafter, the current through the switching circuit drops to the point where it becomes non-conductive, and recharging of the capacitor 46 resumes through resistor 44, at a repetitive rate depending on the R-C constant.

It might also be noted that since the capacitor 46 is charged through the biological load a current reversal takes place between the negative pulsing electrode 32 and the case 12 which has the effect of reducing or eliminating polarization which otherwise occurs when electrodes are pulsed in the same direction in an electrolytic solution.

The diagram of FIG. 7 is essentially for the same circuit as shown in FIG. 6 except for the addition of a constant current element 50 which may comprise a constant current transistor. This circuit is useful to maintain a constant pulse height and rate when the pulsing circuit is used with nucleonic power source whose output decays with time, or with biologically activated power sources whose output varies with the amount of biological activity.

The method of implanting the Pacemaker of the present invention using the improved catheter is illustrated diagrammatically in FIG. 5. The Pacemaker is assembled with the catheter 11 as shown in FIG. 2. The catheter is formed with a fixed or predetermined bend 27' about two to three inches from the end, of about 20°–40° to enable it to turn corners while it is being inserted. The insertion technique itself is essentially the same as currently in use for the transvenous implantation of endocardiac electrodes and other cardiac catherization procedures. The Pacemaker may, for instance, be inserted in the right external jugular vein and advanced through the superior vena cava and through the right atrium into the apex of the right ventricular cavity. This is the position illustrated in FIG. 5*a*. This is accomplished, of course, under fluoroscopic observation.

Prior to attaching the Pacemaker, the effectiveness of its resting position may first be observed with an electrocardiograph to assure that it is functioning normally and that it has captured the heart. The end 28 of the sheath 27 is preferably made of conductive material, such as stainless steel, so that the electrode formed on the body 12 will conduct through the sheath.

Having determined a proper position, the sheath may be partially retracted as shown in FIG. 5*b* to expose the barbs, and the torque tube 25 rotated clockwise to imbed the barbs in the myocardium. The entire Pacemaker, in this condition, will be wedged into the trabeculae making contact both with the case and with the tip electrode 32.

Once attachment in this manner is made, the torque tube 25 may be held against rotation and the rod 23 unscrewed from the internal threads in the nut 24. The entire catheter may then be extracted leaving the Pacemaker imbedded essentially as shown in FIG. 5*c*. The Pacemaker can be extracted from the heart by reversing the foregoing procedure.

The invention is not limited to heart pacing as such. Other examples of the direct implantation of the self-contained stimulator at the site of the stimulation without separate electrical leads include baropacing (stimulation of the baroreceptors in the neck or aortic arch), stimulation of the diaphragm for breathing (stimulation of the phrenic nerve), stimulation of the numerous sphincter muscles which control the flow of various body fluids and solids (at the sphincter site), and other such functions which have been shown to respond to electrical stimulation and which small size and absence of electrical leads would render feasible or more practical. In most such cases the self-contained stimulator described in FIG. 3 would deliver a pulse approximately every 20 milliseconds during activation of the biological function instead of about one pulse per second as in the cardiac Pacemaker. Activation of the pulse train could be accomplished by external command via an electromagnetic or magnetic signal from outside the body.

The invention is not limited to an arrangement which contains an internal source of power. In FIG. 8 there is illustrated an embodiment of the invention which is responsive to hemodynamic pressure. The body section 12*b* is replaced by a flexible or movable section which incorporates a rubber diaphragm or metal bellows 60 which moves under the influence of pressure changes within the heart cavity. Forces and motions arising from such pressure changes are applied to an electromechanical transducer 62 the output of which may be applied to a suitable energy storing circuit 63. The transducer may be of the magnetic induction type or may be a piezoelectric generator. The storage device 63 may be a diode-isolated full-wave-rectifier with capacitor storage. The energy thus stored is available for subsequent release to the stimulation electrodes by a pulse forming circuit substantially as previously described. The storage device will be kept charged by the succession of heart beats and therefore serves the function of the power source previously described.

For example, if the effective area of the movable section 65 is about ½cm², and moves 1mm under the influence of a 20 torr average pressure pulse, each beat would produce about 130 microjoules of mechanical work. Since less than 10 microjoules of electric energy is required for each pulse, a large margin of reserve power is available.

A circuit diagram at FIG. 9 shows an arrangement of the pacer of FIG. 8 adapted as a synchronous pacer, to obtain the benefits from synchronous pacing by slaving the unit to the atriol systole. After storing the large power pulse generated by the transducer during the ventricular contraction, the pulse-forming circuit is "armed;" i.e. it reaches a condition in which the next significant electrical signal from the transducer will cause the circuit to "fire" and deliver an electrical pulse to the stimulating electrodes. Therefore, the pressure impulse from the next atrial contraction is transmitted through the tricuspid valve to generate an electrical signal from the transducer which fires the circuit. The stimulated ventricular contractions thereby become synchronized with the atrial contractions. It may be desirable to construct the circuit so that "arming" is delayed until after the refractory period of the heartbeat to avoid premature firing by reverberations from the ventricular contraction. Also it may be desirable physiologically to provide a delay between the signal

from the atrial contraction and the Pacemaker output pulse, similar to the delay in the A-V node.

FIGS. 10 and 11 illustrate additional arrangements by means of which the heart movement itself can be used to provide a suitable source of energy. Observation has shown that an implanted Pacemaker undergoes transient displacements of about 1cm within a 24th of a second. Assuming constant acceleration, a 5mm displacement relative to the capsule over 1/24th second of an armature weighing 4 grams would produce a force of about 2500 dynes acting over this distance, to produce about 120 microjoules of work per beat, again substantially in excess of the requirements of the Pacemaker. Referring to FIG. 10, a mass 70 is mounted in the manner of a pendulum on the end of a leaf spring 72. The natural oscillation rate of the mass 70 on the spring 72 may be that of the paced heart rate. The lower end of the spring 72 is joint with a magnetic armature 75 received between the poles 76 and 77 of a permanent magnet 78.

The lower end of the armature is retained in a V-shaped recess 79 by the magnetic attraction and is correspondingly formed with a knife or V-edge 80 to provide a pivotal movement. The poles 76 and 77 are spaced apart so that the armature 75 can assume either one of two stable positions, as shown by the full lines and broken lines. In one position, the flux is induced through the armature in one direction while in the other position it is induced in the opposite direction.

Since the pendulum formed by the mass 70 and spring 72 oscillates in resonance with the sinus rate of the heart, the bending moment of the spring 72 lifts the armature 75 from one pole face whereupon it abruptly moves to the opposite pole face, resulting in a sudden reversal of the flux and inducing an electric current in the surrounding coil 82. The coil output may be applied to the storage device 63, as described in connection with FIG. 8. FIG. 11 is similar to FIG. 10 except that the mass 70' and the spring 72' are connected to stress a piezoelectric crystal 85. In this embodiment, the periodic rate of the mass and spring may be substantially greater than that of the heart, to produce a "ringing" effect with each beat.

Certain of the teachings and advantages of the present invention may be used to improve the performance of existing pacemakers which presently use endocardinal electrodes. The body Pacemaker 10 may be modified for this purpose to perform the function of the electrodes only and an arrangement for this purpose is illustrated at 100 in FIG. 12. In this case, the cartridge body 112 is made similarly to the body 12 except that it does not contain any pulsing circuitry or power source, but merely comprises means for making electrical contact. Thus, the body 112 may conveniently be made to a smaller length and/or diameter than that which has previously been described. The outer surface of the body 112 thus comprises one of the electrodes, while stimulating electrode 132 may be made and supported on a ceramic pedestal spaced from the body 112 in the manner which has been described in connection with the electrode 32 of FIG. 3.

The electrode assembly 100 will be connected by flexible leads to a conventional remote pacer by means of a flexible electrical conduit or lead 122. The lead 122 may be a coaxial conductive cable, which has one of its leads connected to the case or body 112 and the other connected to the electrode 132. The assembly 100 may be used with remote pacers which employ a single electrode lead or a pair of leads. Where a single lead is used, it would be connected inside the body 112 to the electrode 132.

The electrode assembly of this invention is provided with a somewhat modified form of attachment comprising a pair of generally axially extending retaining wires 115 and 116. The forward ends of the wires are attached or secured to the body 12. The wires extend rearwardly and outwardly, and are movable between a retracted position in which the wires lie adjacent to the outer surface of the body, to a spread apart position, substantially as shown.

The general technique of inserting and implanting the electrode assembly 100 does not differ substantially from that described in connection with the pacemaker 10. The torque tube 25 and the sheath 27 may be used, with the rod 22 removed. The cylindrical conductive end 28 would be received partially over the body 112 with the attaching wires 115 and 116 collapsed and retained within end 28. The electrical lead 122 is threaded through the hollow torque tube 25.

It would be expected that the electrode assembly would be inserted well into the apex of the ventricle cavity accompanied by some stretching of the heart muscle. The torque tube 25 could be employed to provide axial forces as well as rotational alignment. The sheath 27 would then be retracted exposing the ends of the attachment wires 115 and 116, and when the axial force is released the ends of the wires would tend to imbed themselves within the heart muscle. If necessary, some pull could be placed on the lead 122 to complete the attachment, and then the catheter may be extracted leaving the electrode assembly 100 in place.

The electrode assembly 100 provides to a remote Pacemaker certain of the advantages of the present invention. Principally, the electrodes, which are formed as integral and discrete surface portions of the assembly, are not prone to dislodgement, movement, penetration or breakage. Further, they define regions of stimulation which are spaced from the region of attachment, as in the case of the Pacemaker 10, and thus remain free of the adverse affects of fibrosis.

It is accordingly seen that this invention provides a novel self-contained biological stimulator, which is particularly adapted for use as a Pacemaker, and an electrode assembly useful with existing Pacemakers. It is intended for long-term treatment of partial or complete A-V block. Synchronous pacing may be used, as desired, and the circuit can be modified as known in the art for demand pacing. For synchronous pacing of devices of the types of FIGS. 3, 10 or 11, a short sensing or trigger electrode wire may extend axially from the rear wall 24' of the body 12b through the tricuspid valve into the right atrium to pick up the atrium pulse as a control signal for the circuit 30. For demand pacing, the surface electrode 32 may be used to pick up the ventricle pulse and suppress the trigger circuit in the manner taught for example by Keller U.S. Pat. No. 3,431,912 or Greatbatch U.S. Pat. No. 3,478,746. The physical size of the capsules which form the bodies is sufficiently small to permit long-term treatment, such as in the case of a child. The apparatus and method of the attachment and implanting is one which results in minimum discomfort to the patient. In the event of failure, the size of the Pacemaker is sufficiently small to make it feasible to simply leave it in place and to insert

a new one, although intervenous removal by catheter also is possible.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus, and that changes may be made therein without departing from the scope of the invention.

What is claimed is:

1. A stimulator device for insertion in a living body and having particular advantage for intracardiac use comprising a structure having a body form for transvenous or transarterial insertion, electrode means on the surface of said body form for contact with a portion of the living body to be stimulated by said electrode means, and means mounted to project outwardly of and peripherally of said body form including anchor portions locating in a position displaced from said electrode means and providing means for engaging in portions of said living body to establish said electrode means in a required position of use, said electrode means having in connection therewith means to energize the same once said body form is located in its required position of use.

2. A stimulator device as in claim 1 wherein said means to energize said electrode means includes a power source positioning in a location remote from said body form.

3. A stimulator device as in claim 1 wherein said means to energize said electrode means includes a power source embodied within said body form.

4. A stimulator device as in claim 1 wherein spaced surface portions of said body form define separate electrode means.

5. A structure as in claim 1 wherein said anchor portions are defined b wire like segments connected with and biased to normally project outwardly from said body form to facilitate the establishment of a connection thereof with said living body in an area displaced from said electrode means.

6. A stimulator device as in claim 1 wherein said electrode means have a fixed positioning in respect to said body form and comprise at least two electrodes, and said body form includes insulator means separating said electrodes.

7. A stimulator device as in claim 1 characterized by said body form being a unitized structure having means for guiding the same for transvenous or transarterial insertion.

FIG-1

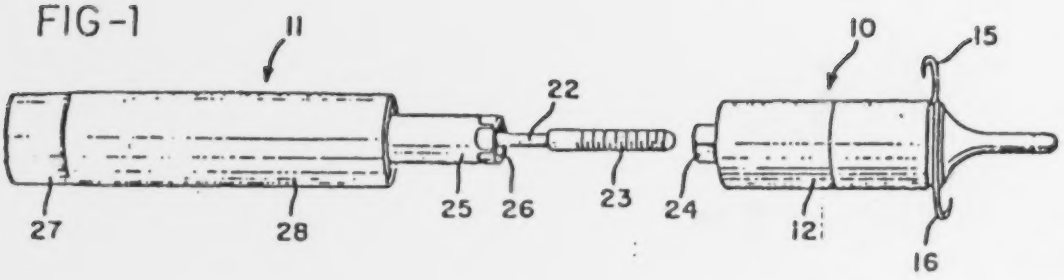


FIG-2

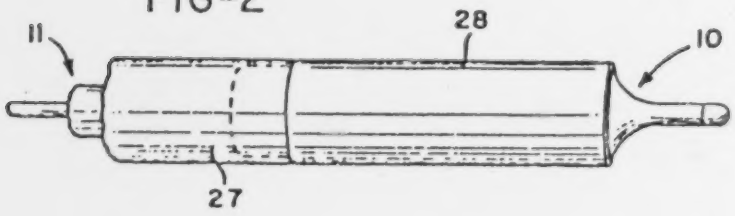


FIG-3

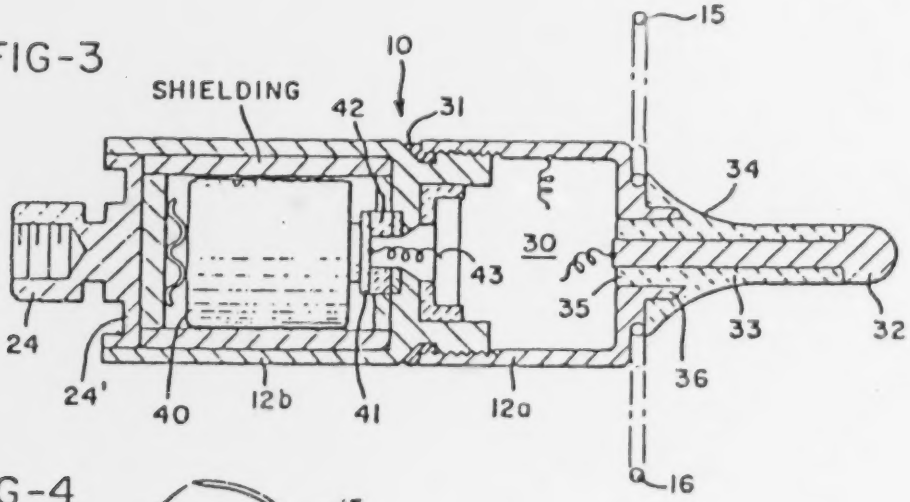
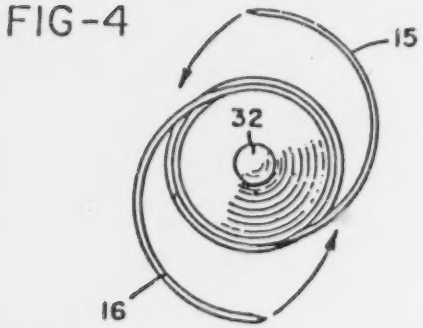


FIG-4



INVENTORS
NED S. RASOR &
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BY
Marschal, Bibel, French & Bugg
ATTORNEYS

Ex.-15

FIG-5A

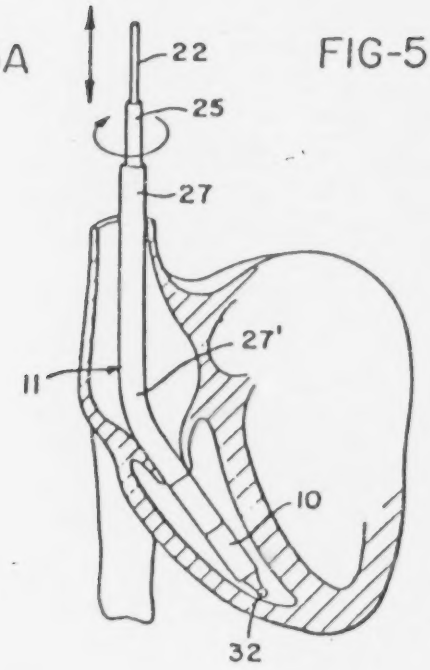


FIG-5B

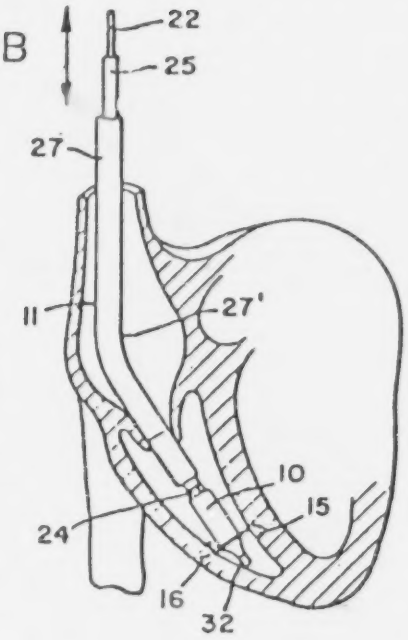


FIG-5C

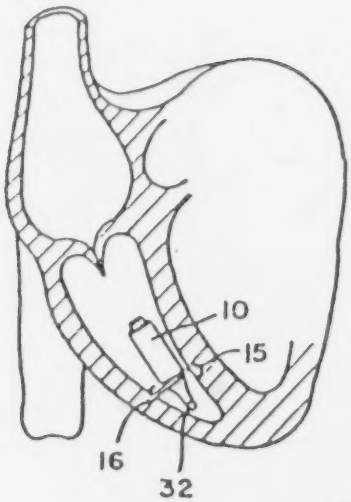


FIG-6

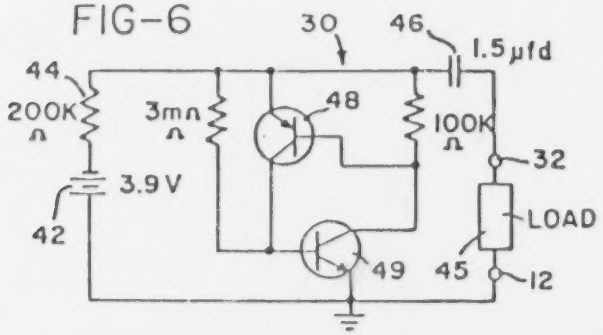
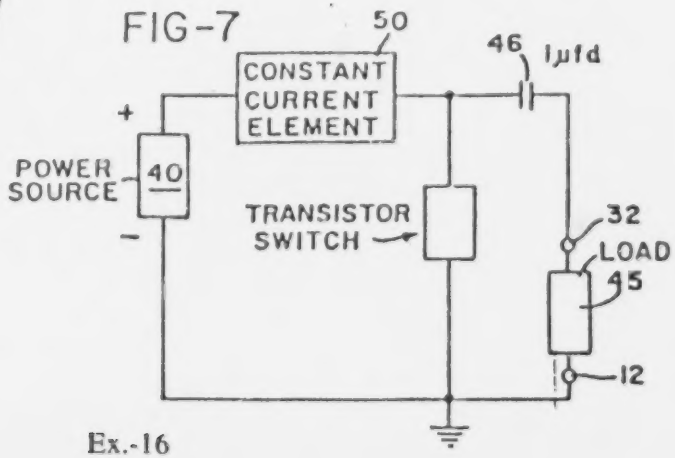


FIG-7



Ex.-16

FIG-8

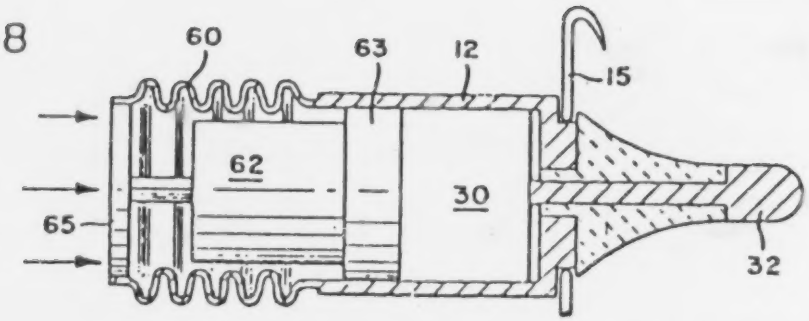


FIG-9

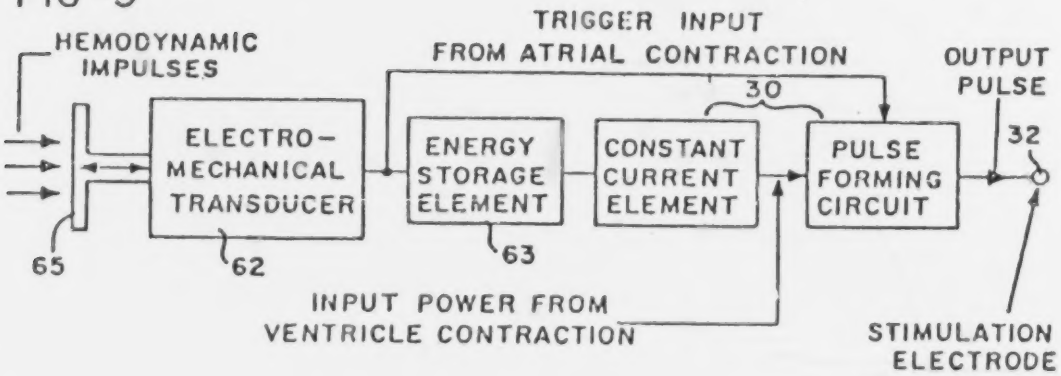


FIG-10

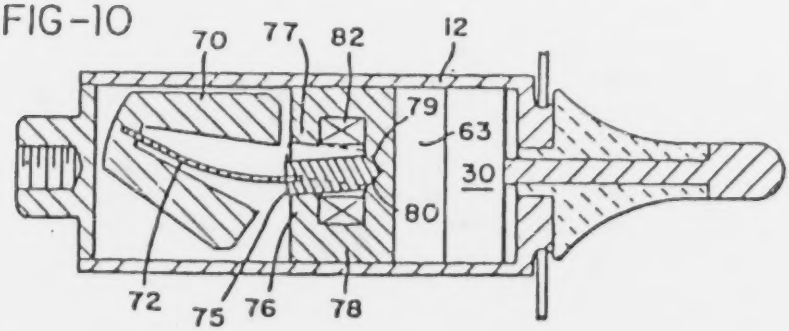
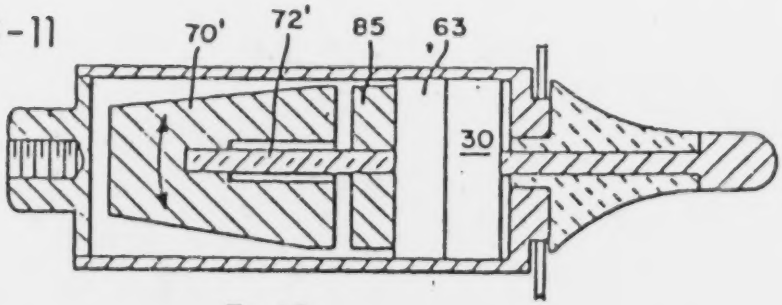
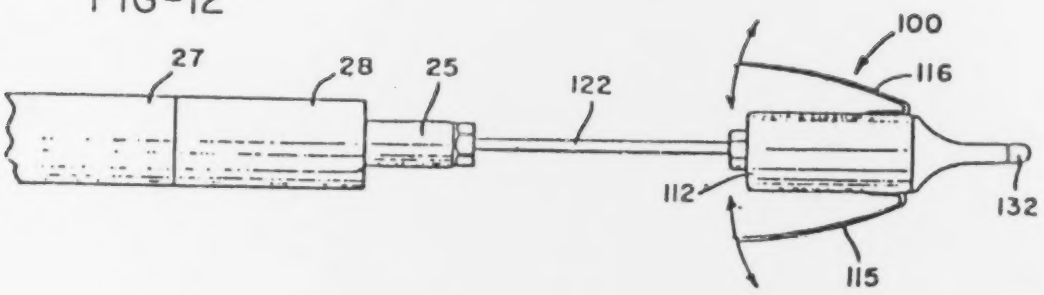


FIG-11



Ex.-17

FIG-12



UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,835,864 128 Dated September 17, 1974

Inventor(s) Ned S. Rasor and Joseph W. Spickler

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 5, line 6, "activity" has been corrected to read -- cavity --;

line 16, "preferred" has been corrected to read -- preferably --.

Col. 6, line 32, "radiosotope" has been corrected to read -- radioisotope --.

Signed and sealed this 18th day of February 1975.

(SEAL)
Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents
and Trademarks

NEW PACEMAKER ELECTRODES

Max Schaldach

For the long-term treatment of a large variety of disturbances in the conduction system of the heart, the electric cardiac pacemaker has proved superior to any other therapy. The only disadvantage today is its relatively short time of operation, determined by the limited capacity of the commonly used zinc-mercury oxide elements. An increased life time can be achieved if either new power sources with a better energy density to volume ratio or new stimulation electrodes are available which prevent the waste of energy due to polarization effects. It is the object of this paper to describe a new pacemaker electrode with respect to low power consumption in the long-term therapy of patients. Primary attention will be focused on the electrochemical problems of the solid-heart tissue interface. In addition, technical details of a new atrial sensing catheter electrode will be discussed, which has small wire hooks at its tip for attaching it to the endocardial surface.

MATERIALS AND METHODS

The behaviour of metals employed as stimulation electrodes is of considerable interest in experimental medicine and biomedical engineering, particularly in such applications as cardiac pacemakers. In most commercial pacemaker electrodes the material used so far is either platinum-iridium or elgiloy, an alloy containing cobalt, nickel, molybdenum, manganese, iron, carbon, and berillium. These electrodes are either sutured into the muscle of the heart or inserted into the right ventricle by means of a transvenous catheter. The energy required to stimulate the heart depends on the electrode and is usually 1-5 μJ when the pacemaker electrode is first implanted. The electrical behavior of the tissue around the stimulation electrode and the effect of the electrode upon it can be evaluated from the stimulation threshold and the operational value of the electrode circuit. The term threshold means the smallest amount of electrical energy which will produce consistent cardiac contraction with the electrode system used, when the stimulation impulse falls past the absolute and the relative refractory period of the heart.

In Figure 1 a typical threshold curve is shown using an elgiloy catheter electrode connected to the output circuit described in the drawing. The myocardial threshold increases during the first weeks of implantation caused by interstitial edema and the growth of connecting tissue around the catheter tip. In metallic electrodes the stimulation energy cannot be substantially reduced by changing the surface area of the electrode or the impulse duration.

Since a high current density vs. a high electric field strength at a small electrode is required locally to stimulate the cardiac muscle, several polarization voltages are developed with the consequence that most of the delivered energy from the pacemaker circuit is wasted in the electrode electrolyte interface. This is particularly important in the case of implanted pacemakers since their life time is determined by the energy stored in their batteries. Considerable improvement of the life time could be achieved if the stimulation system worked more economically.

The electrochemical reactions in the electrode interface are very complex and involve possible electrode corrosion, gas evolution, and oxydation vs. reduction of metabolites with potentially toxic effects on a long-term basis[1].

It is recognized that ideally the processes taking place at stimulation electrode surfaces probably should be solely those involving motion of electric charges without any irreversible chemical reaction taking place. To demonstrate the electrochemical aspects in Figure 2, the potential model of a metal electrode in contact with the endocardium is shown. The potential distribution in the interface gives a simplified overlook of the electrochemical behavior under steady state conditions. The potential depends on the distance from the electrode surface and is made up of the drop in the rigid Helmholtz-double layer, the space charge region, and the membrane potential. The diffusion potential represents the electrical changes between the excitable membrane and the electrode surface. Thus, the rise in stimulation threshold can be expressed in this portion of the potential distribution, so that an increase in the thickness of the connective tissue layer results in a threshold rise. The electrical performance can be described in the equivalent circuit. Because of the non-linearity of electrochemical processes, the value of each component is a function not only of the time but also of the applied electrode voltage V_E[2].

To demonstrate the electrochemical polarization of metal pacemaker electrodes in Figure 3, the current density vs. electrode potential curves for platinum and elgiloy are shown. During polarization the change of the electrode potential results as well in the Helmholtz-potential as in the potential drop of the diffusion layer. This results in an energy loss of charging and recharging the Helmholtz capacity. When the applied electrode potential rises above a critical value (Figure 4), ions discharge, chemical reactions take place, current flows across the interface, and the electrical energy is now irreversibly wasted. As a result of this current flow, the field strength necessary for triggering the next excitable cardiac membrane breaks down. The stimulation occurs only

From the Department für Biomedizinische Technik der Friedrich Alexander Universität, Erlangen-Nürnberg

Trans. Amer. Soc. Artif. Int. Organs, 1971

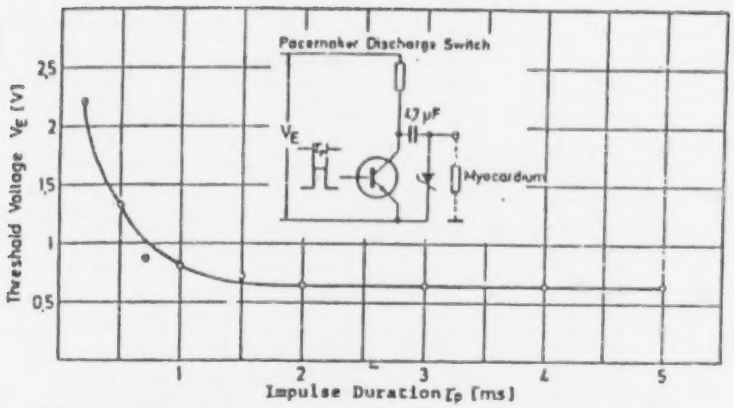


Figure 1. Threshold voltage vs. impulse duration for intracardiac electrodes in humans (initial stimulation in the right ventricular apex).

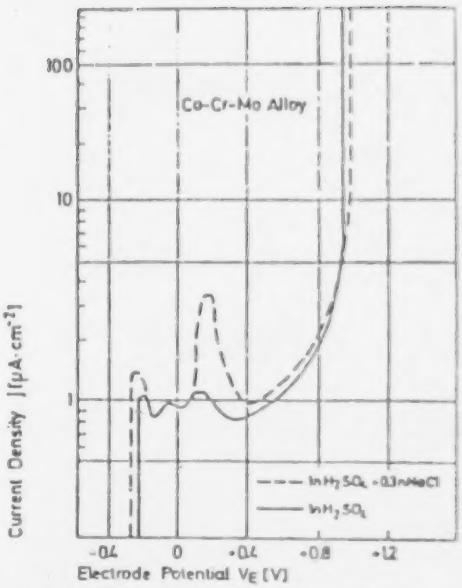


Figure 3. Anodic polarisation of a Co-Cr-Mo stimulation electrode.

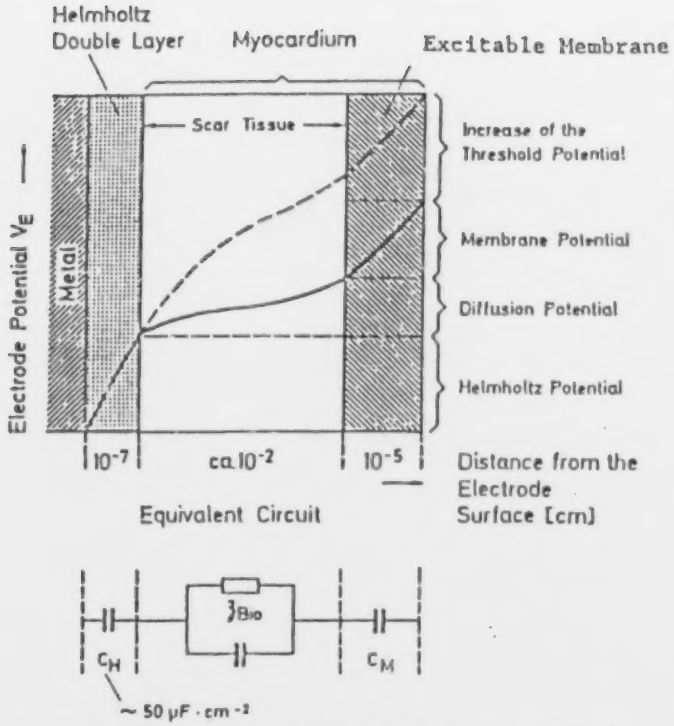


Figure 2. Potential distribution and electrical properties of the metal/ myocardium interface.

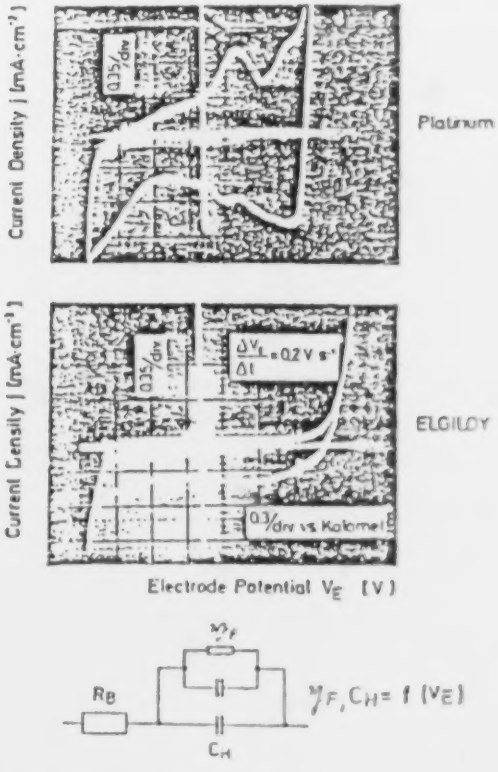


Figure 4. Pt- and elgiloy-stimulation electrodes in physiological saline solution.

as the result of a change in ion concentrations due to a current flow near the excitable membrane. The Faraday-impedance, F, now determines the electrochemical behavior.

The DCD electrode. One way to avoid the wastage of energy due to polarization effects has been discussed by Parsonnet[3] using a so called "Differential Current Density Electrode." In this system there is a low current density at the metal to avoid polarization and a high current density at the contact to the endocardium to produce a significant fieldstrength to activate responsible cells. As a result, stimulation thresholds are found whose energy is 1/10 of that achievable with conventional metal electrodes. Figure 5 shows the dimensional drawing of the DCD electrode. The electrochemical behavior is demonstrated in the current density vs. electrode potential curve of Figure 6. The shape is determined by a current-limiting resistor, R_H, in series, as described in the equivalent circuit below. The value of the internal resistor ranges from 2-4 Kohms. The only disadvantages of this method are difficulties in stable fixation of the electrode, and electrochemical instability due to the development of fibrotic tissue within the chamber.

The dielectric pacemaker electrode. To prevent electrochemical reactions, a thin dielectric layer is used on the surface of a metallic electrode tip (Figure 7). The passage of an electrical pulse through the interface of such a coated electrode involves only a change of the charge distribution in the metal and ions in the electrolyte. Charge transport is now possible through the oxide-film. That means no faradaic reactions can occur, and as a consequence, such a system avoids electrochemical reactions such as electrode corrosion, gas evolution, and reactions with metabolites. The potential model of this electrode and its equivalent electrical circuit is shown in Figure 8. The equivalent circuit of this electrode must be completed by an additional in-series capacitor of the same magnitude as the Helmholtz-capacitance. The current density vs. electrode potential curve in Figure 9 demonstrates the electrochemical behavior of this dielectric pacemaker electrode. In the electrode potential range below 1 V vs. calomel, the electrode acts as a pure capacitor. This results in the fact that a part of the delivered pulse energy is also lost due to the fact that the charge stored in the capacitor during a pulse is not utilized for stimulation.

The electrodes consist basically of a metal tip which is coated by a thin dielectric layer of electrochemically deposited tantalum oxide. A helical elgiloy wire is used for connection to the pacemaker pulse generator. Silastic medical grade tubing has so far been used as encapsulating material. In Figure 10 the dielectric pacemaker electrode for transvenous stimulation is demonstrated in comparison to the DCD, the Elema-platinum, and the Biotronik-elgiloy electrode.

RESULTS

Preliminary studies with various models of dielectric stimulation electrodes in animals confirmed the in vitro results that stimulation thresholds are 3 times lower than those measured with standard metal electrodes. Therefore, it appeared that the transvenous model was acceptable for clinical trial. The electrode was inserted through the cephalic vein into the right ventricular apex. In 5 patients the electrodes were attached to external pacemakers and stimulation thresholds were tested until the electrodes were removed and replaced with conventional elgiloy-electrode catheters. The preliminary results in clinical application confirmed that no electrochemical reactions occur. The required threshold energy is 1/3 of the energy that is required in the use of metal electrodes of similar geometric size. No change in the capacity of the dielectric layer could be observed.

As an advantage, in comparison to the DCD electrode, the dielectric pacemaker electrode allows more safety for satisfactory contact to the myocardium. The animal experiments, as well as the clinical results, suggest the feasibility of this new pacemaker electrode. The low energy requirement may improve pacemaker technology by reducing the number of batteries and thus the pacemaker size, or by increasing pacemaker life time with the present number of batteries.

The atrial sensing electrode. The atrial synchronous pacing acts as an artificial conduction system. It is the most physiologically responsive mode of pacing today. Although this method was introduced relatively early in the evolution of cardiac pacing[4], in practice, the percentage is about 5% of all cases treated, which contrasts with the hemodynamic advantage. Judging from these results, the implantation procedure seems to be compared with transvenous pacing. The first and still most widely used thoracotomy must be recognized as an excellent method for stable atrial synchronous pacing. However, this approach is more difficult, traumatic to the myocardium, and entails a high risk, particularly for aged patients. Therefore, in the past years, an attempt was made to avoid the thoracotomy technique. In 1966, Carlens and Lagergren[5-6], published the method of fixing the atrial sensing electrode transmediastinally by means of a mediastinoscope. This method was only successful if the electrode tip was placed well against the posterior atrial wall and does not move during the early period of healing.

Another method, the retrosternal approach, is described by Bruck[7] and Dittrich[8]. Through a subxiphoid incision, the right ventricle is approached, and both the ventricular stimulating and the atrial sensing electrodes are sutured to the right ventricle and to the right atrium. This method offers no significant advantages over the thoracotomy.

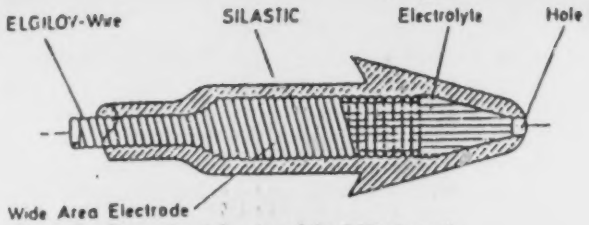


Figure 5. Dimensional drawing of the DCD electrode.

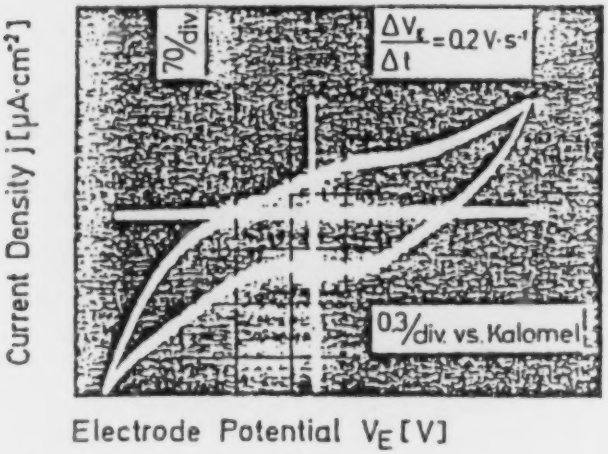


Figure 6. Current density vs. electrode potential curve.

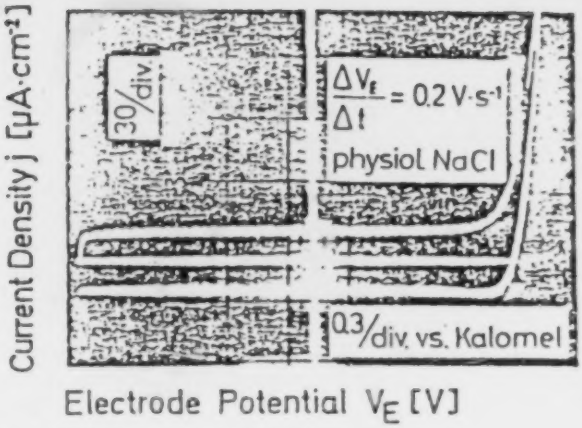


Figure 9. Current density vs. electrode potential curve.

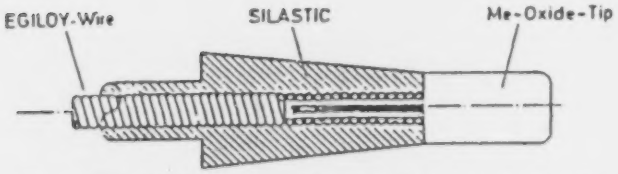


Figure 7. A thin dielectric layer is used on the surface of a metallic electrode tip.

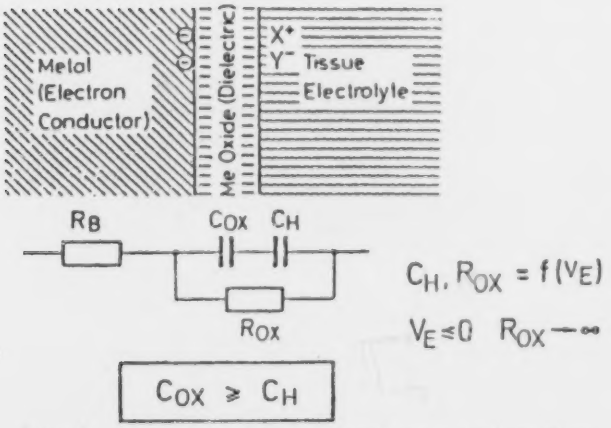


Figure 8. Potential model of electrode and its electrical equivalent circuit.

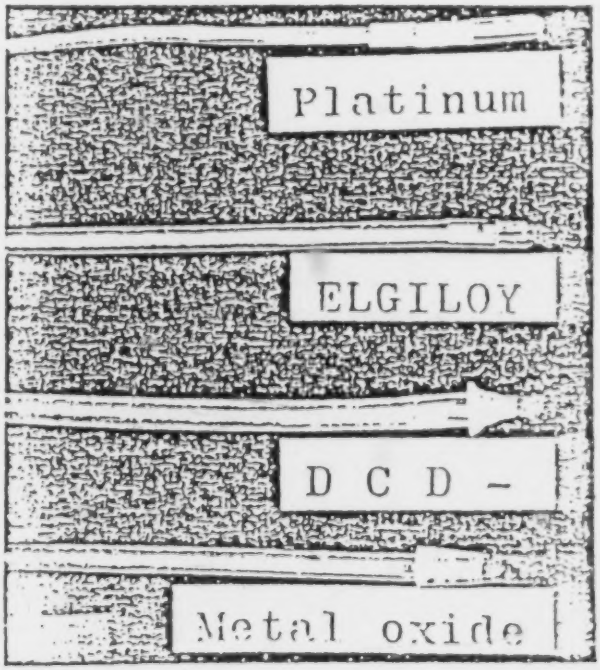


Figure 10. The dielectric pacemaker electrode for transvenous stimulation is compared to the DCD, the Elema-platinum, and the Biotronik-elgiloy electrode.

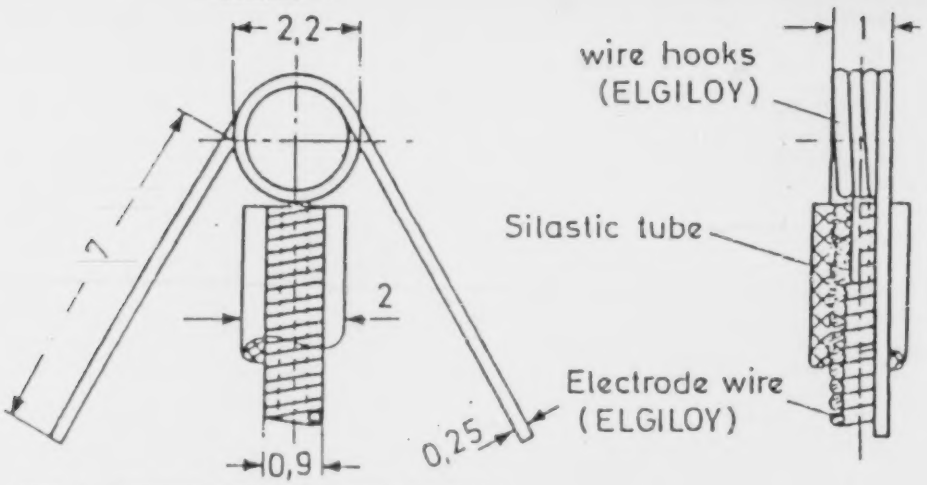


Figure 11. Dimensional drawing of the sensing catheter tip.

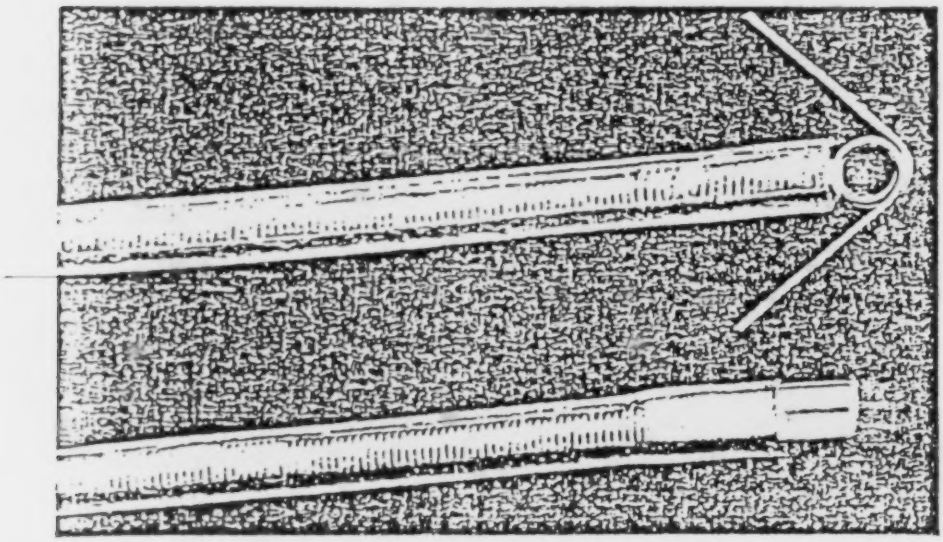


Figure 12. The atrial and ventricular electrode.

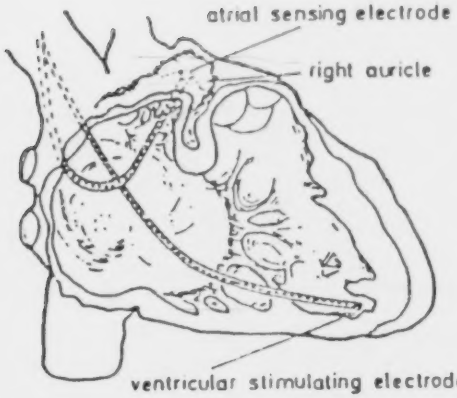


Figure 13. Atrial synchronous pacing, transvenous placement.

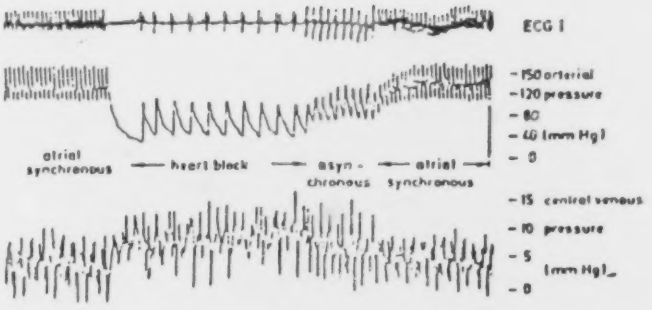


Figure 14. Increase in mean systolic pressure and decrease in central venous pressure.

In addition, the use of atrial sensing catheters has already been reported[9,10]. Straight atrial electrodes were used with high input-sensitive pacemakers, but stable synchronization could not be achieved[9-11]. Better results were obtained by the application of curved atrial electrodes[10]. When these electrodes are properly positioned with the right atrium, a more stable synchronization than with the straight electrodes was found[9,12]. However, this method as well as our own experience[13] with a precurved electrode, where the sensing and stimulation electrode are fixed by a platinum double ring and placed in the atrium, do not satisfy the requirements for safe synchronous operation. Bruck[7] suggests the possibility of utilizing the transseptal puncture technique for fixing a transvenous sensing electrode into the area of the fossa ovalis. However, no clinical experience is available as yet.

This paper will present an intraatrial catheter technique for the stable fixation of the sensing electrode tip into the atrial appendage[14,15]. To maintain permanent contact with the atrial endocardium, the electrode tip is provided with fine wire hooks so that it can be firmly anchored between the trabeculae of the right auricle.

Figure 11 shows the dimensional drawing of the sensing catheter tip. A picture of both the atrial and the ventricular electrode is shown in Figure 12. Both electrodes are made of an elgiloy helical coil insulated by a silicone rubber tube terminating in a cylindrical tip, or a wire hook, made of the same elgiloy material. To ensure high flexibility, the wire hooks are turned in a relief loop. This design provides sufficient safety in cases of electrode removal via a guiding tube. The stiffness of the electrode can be varied by introducing an additional guiding wire into the lumen of the helical coil.

The application of this technique for atrial synchronous pacing requires a precurved guiding catheter as protection against injury to the veins, atrial wall, and tricuspid valve. The catheter is made of radiopaque teflon tubing. Any vein of proper diameter at the root of the neck or in the pectoral region can be used for entry into the venous system. In most cases, the right external jugular and the cephalic vein are satisfactory or, if these are of inadequate diameter, the internal jugular vein can be used. Once the position of the guiding tube is correct, the atrial sensing electrode is advanced through the tube into the appendage up to the point where the end of the wire hooks are still inside. Further advancement of the electrode will release the wire hooks to anchor in the trabeculae of the right atrial appendage, where P-wave potentials normally exceed 5 mV. The placement is conventional in every regard. The final position of both electrodes in the heart is demonstrated in Figure 13.

Clinical experience. Atrial synchronous pacing applied according to the aforementioned method was clinically applied in 68 patients; ages ranged from 12 to 70 yr with a mean of 60 yr. Arteriosclerosis obliterans has been quoted as the main cause of total AV-block in the presented case material. Much less common as etiologic factors are congenital cardiac defects, infections, and degenerative diseases. The majority of treated patients were between 60-70 yr, and implantation via thoracotomy of the atrial synchronous system is not acceptable for this group. The transvenous approach seems to be the only method combining the advantage of using transvenous pacing and atrial synchronizing. The clinical results gained since August 1968 demonstrate the benefit of this method. The long-term results have shown the hemodynamic importance of the atrial contribution to cardiac output especially in those cases with disease. The improvement in cardiac function is demonstrated by the increase in mean systolic pressure and decrease in central venous pressure as indicated in Figure 14.

SUMMARY

The main clinical application of stimulating electrodes today is for use in cardiac pacemakers. The electrode materials exclusively used so far are noble metal alloys (e.g. Pt/Ir) or stainless steels (e.g. elgiloy, an alloy containing Co, Cr, Ni, Mo, Mn, Fe, C, and Be). The problems besetting these metallic electrodes are 2 kinds:

1. Since a high current density and a small electrode is required locally to stimulate the cardiac muscle, several polarization voltages are developed with the consequence that most of the stimulating energy is wasted at the electrode electrolyte interface. This is particularly important in the case of implanted pacemakers since their life time is given by the energy stored in their batteries. Considerable improvement in longevity could be achieved if the electrodes worked more economically.
2. The electrochemical reactions in the electrode interface are very complex and involve possible electrode corrosion, gas evolution, and oxydation vs. reduction of metabolites with potentially toxic effects on a long term basis.

It is recognized that ideally the processes taking place at physiological electrode surfaces probably should be solely those involving motion of electric charges without any irreversible chemical reaction taking place. The application of such a non-polarizing electrode was reported by Parsonnet, who achieved a reduction of the stimulation energy down to 1/10 of the energy that is required in the application of metal electrodes. The disadvantage of this electrode was found in its instability during long-term operation.

To avoid this disadvantage a purely capacitive electrode was developed and tested in vitro and in vivo. This electrode consists of a metal which is covered by a thin dielectric oxide film. The application of an electrical impulse through the interface involves only a change of the charge distribution and the required fieldstrength

for triggering the next excitable membrane in the conduction system of the heart. The application of catheter electrodes with oxide layers in animal experiments as in clinical tests confirmed that no electrochemical reactions like corrosion, gas evolution, and reaction with metabolites occur. Only a thin fibrotic layer could be observed and the capacity always remains stable. The required energy to stimulate the heart is 1/3 of the energy that is required in the application of metal electrodes of similar geometric size.

In addition, a new electrode catheter is demonstrated which has small wire hooks at its tip for fixing it to the endocardial surface. This method has been successfully used in 68 patients for fixation of the pick-up electrode in the right auricle of the heart for atrial synchronous pacing.

REFERENCES

1. Greatbach, W., Piersma, B., Shannon, F. D., and Calhoon, S. W., Jr. Polarization phenomena relating to physiological electrodes. Ann. N. Y. Acad. Sci. 167:722, 1969.
2. Schaldach, M. Fortschritte in der Schrittmachertherapie. Verhandl. Dtsch. Ges. f. Kreislaufforschung 35:229, 1969.
3. Parsonnet, V., Zucker, I. R., and Gilbert, L. Clinical use of a new transvenous electrode. Ann. N. Y. Acad. Sci. 167:758, 1969.
4. Nathan, D. A., Greenberg, J., Madariage, N., Daughtry, D. C., Falvre, G. R., and Dodinot, B. P. Intrapericardial pacemaking. J. Electrocardiol. 1:163, 1968.
5. Lagergren, H., Johansson, L., Karlöff, J., and Thomander, H. Atrial-triggered pacemaking without thoracotomy: Apparatus and results in twenty cases. Acta Chir. Scand. 132:678, 1966.
6. Carlens, E., Johansson, L., Karlöff, J., and Lagergren, H. New method for atrial-triggered pacemaker treatment without thoracotomy. J. Thorac. Cardiovasc. Surg. 50:229, 1965.
7. Bruck, A. Differentialtherapie mit verschiedenen Herz-Schrittmachertypen. Verhandl. Dtsch. Ges. f. Kreislaufforschung 35:140, 1969.
8. Dittrich, H. Pericardiotomia inferior longitudinalis. Chir. Praxis 13:563, 1969.
9. Dodinot, B. P., Petitier, H. A., Gilgenkrantz, J. M., and Falvre, G. R. Clicical experience with atrial-synchronous pacing. Ann. N. Y. Acad. Sci. 167:1038, 1969.
10. Rodewald, G., Giebel, O., Harms, H., and Scheppokat, K. D. Intravenös-intrakardiale Applikation von vorhofgesteuerten elektrischen Schrittmachern. Zschr. f. Kreislaufforschung 53:860, 1964.
11. Falvre, G. R., Sarnoff, S. J., Mitchell, J. H., and Linden, R. J. Synchronicity of ventricular contraction observations comparing hemodynamic effects of atrial and ventricular pacing. Brit. Heart J. 15:299, 1963.
12. Center, S., Samer, P., and Castillo, C. Synchronous, standby, and asynchronous pervenous pacing of the heart. Ann. Thorac. Surg. 5:695, 1968.
13. Schaldach, M., Bücherl, E. S., and Franke, O. Implantierbare elektrische Schrittmacher zur Langzeittherapie von Reizleitungsstörungen des Herzens. Acta Medicotechnica 15:240 and 286, 1967.
14. Schaldach, M. Entwicklungsaussichten der Schrittmacherbehandlung in technischer Hinsicht. Verhandl. Dtsch. Ges. f. Kreislaufforschung 35:127, 1969.
15. Rosenkranz, K. A. and Schaldach, M. Transvenös-endokardiale Vorhofsteuerung von Schrittmachern. DMW 96:680, 1971.

P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoracotomy

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A new technique for the transvenous implantation of a specially designed atrial sensing electrode is described. In combination with a ventricular stimulating electrode and an atrial-controlled pacemaker, the method enables synchronization of atrial with ventricular activity. The atrial sensing electrode is put into the right atrial appendage through a preshaped radiopaque Teflon applicator catheter. Two hooks on the electrode tip provide for safe and secure anchoring of the electrode tip to trabeculae of the atrial appendage. The technique has been used for synchronous P wave pacing in 12 patients with complete atrioventricular block, most of them suffering from Adam-Stokes attacks. Three additional patients with sinoatrial block were treated by means of anchored atrial electrodes. Observation periods of up to 39 months showed no dislocation of any of the anchored atrial electrodes, and performance in all patients was faultless.

Of the different methods for implanting electrical pacemakers, the transvenous-endocardial technique has come to the fore in recent years. This approach is superior to the use of myocardial and epicardial electrodes since the surgical risk is considerably reduced, inasmuch as the pacemaker is implanted under local anesthesia without need for either thoracotomy or pericardiotomy. The method thus far has been used with pacemakers equipped with a single ventricular electrode, as in fixed-rate and ventricular-controlled pacing.

Atrial-controlled pacemakers, with 1 sensing electrode in the atrium and 1 ventricular electrode, have so far been placed transthoracically. The need for major surgery may explain the relatively infrequent use of atrial synchronous pacemakers in most hospitals, although their use in comparison with fixed-rate pacemakers provides physiologic coordination between atrial and ventricular activity and adjustment of the heart rate to the imposed load.

Gilmore et al.[1] and Samet et al.[2] reported that with synchronized pacing the cardiac output increased beyond that achieved through asynchronous ventricular pacing by about 20 percent of the initial value. Therefore, atrial-controlled pacemakers seem to be desirable in most patients. Their use should not be limited to younger, still working patients, since they are of particular value to aged patients with established cardiac damage. The obvious advantages of atrial synchronous pacemaking justify past efforts to develop techniques for atrial detector electrode implantation by which thoracotomy can be avoided. In 1965, Carlens et al.[3] reported a method of transmediastinal implantation of the atrial sensing electrode by means of a mediastinoscope. In 1967, Schaldach et al.[4] recommended a transvenous-endocardial approach to the heart, the control electrode being attached by means of platinum rings to a common ventricular electrode. Smyth et al.[5] implanted hook-shaped prestressed atrial elec-

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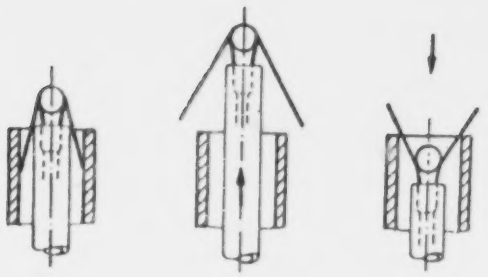


Figure 1. Nonoperatively implanted transvenous anchored atrial electrode: tip construction, introduction, fixation and means for removal.

trodes. Similar procedures have been described by Dodinot et al.,[6] Faivre et al.,[7] Rodewald et al.,[8] Kramer and Moss,[9] Kastor et al.[10] and Castillo et al.[11]

The foregoing techniques have not had wide clinical use, since none provides means for stable fixation of the sensing electrode in the atrium. Bruck[12] suggested that atrial sensing electrodes could be applied by transseptal puncture technique, but clinical experience with this technique has not yet been reported. Our group has devised, and first used in man in August 1968, a technique enabling safe fixation in the right atrium of a transvenously introduced atrial sensing electrode.

Method

The tip of the sensing electrode is shown in Figure 1. The feed unit of the electrode catheter consists of an Elgiloy spiral. The electrode tip is formed by 2 fine wire hooks of the same material, each ending in a relieving loop, thus providing the necessary flexibility to the hooks. The insulating material used for the catheter electrode is silicone rubber. The sensing electrode has at its tip 2 fine hooks or barbs, each 7 mm long. These are used to anchor the tip of the electrode in the trabeculae of the right atrial appendage.

The "fishhook" electrode catheter is introduced through the exposed external jugular vein, which is ligated peripherally, and, over the properly positioned anchored electrode. The internal jugular vein may be used when necessary, in which case the vein is closed and the electrode stabilized by means of a single purse-string suture.

Needed instruments include a guide wire (0.9 mm by 150 cm), a radiopaque, conically tipped polyethylene catheter (8F, 80 cm), and an applicator tube of radiopaque Teflon® (Cook, Bloomington, Indiana, TRT, 12F, 45 cm). The applicator is a pre-curved metal rod with a hook-shaped tip (Fig. 2).

The implantation is performed as follows: First, the guide wire is passed during fluoroscopy by way of the open vein into the right atrium, and the 8F catheter and outermost 12F applicator tube are passed over it. When the wire and inner catheter are removed, the end of the Teflon applicator, now resting in the right atrium, regains its hook shape and can then be manipulated by rotation into the atrial appendage (under fluoroscopic control), and its position checked by the injection of contrast medium. The

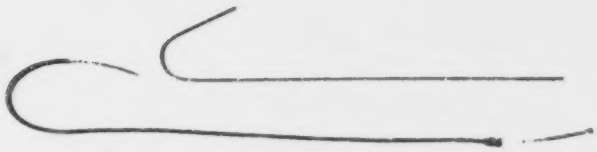


Figure 2. Applicator catheter. **Above,** curved wire for preshaping catheter. **Below,** curved applicator catheter with coaxial inner polyethylene catheter.



Figure 3. Atrial sensing electrode and ventricular stimulation catheter placed without thoracotomy.

barbed electrode, lubricated by silicone oil and stiffened by a mandrel, is introduced through the lumen of the applicator. During its introduction, 2 barbs or hooks on the end of the electrode are pressed together. When the tip of the electrode leaves the applicator, these hooks are freed to unfold within the appendage and anchor its trabecular system. The applicator is carefully withdrawn over the electrode catheter, slight forward pressure on the electrode protecting its connection in the appendage. The stiffening wire mandrel is then withdrawn. If the electrode barbs are inadvertently detached from the atrial appendage during mandrel removal, reanchoring is done by repositioning the curved applicator tube.

Should an unanchored sensing electrode be swept into the ventricle, it can easily be drawn close to the applicator in the atrium. If an electrode is to be exchanged for another, it can easily be removed through the applicator since the hook spreading mechanism is reversible.

The ventricular stimulation catheter electrode, put in through a cephalic vein, is routinely inserted before the sensing electrode for reasons of safety (Fig. 3). The procedure is performed with the patient heparinized. Connection to the infraclavicular-implanted, atrial-controlled pacemaker is made after measurement of the atrial activity potential and a performance check of synchronous stimulation.

Trigger sensitivity of the Biotronik-IVP-pacer is set at 0.5 mv, a level appropriate to the signal picked up by the atrial sensing fishhook electrode. Despite the relatively high input sensitivity, interference is not significantly increased, since the pacemaker is encapsulated in a case of austenitic chromium-nickel-molybdenum steel, which acts as the indifferent electrode in the stimulation circuit.

The signals from the atrial sensing electrode after amplification are used to trigger a monostable multivibrator.

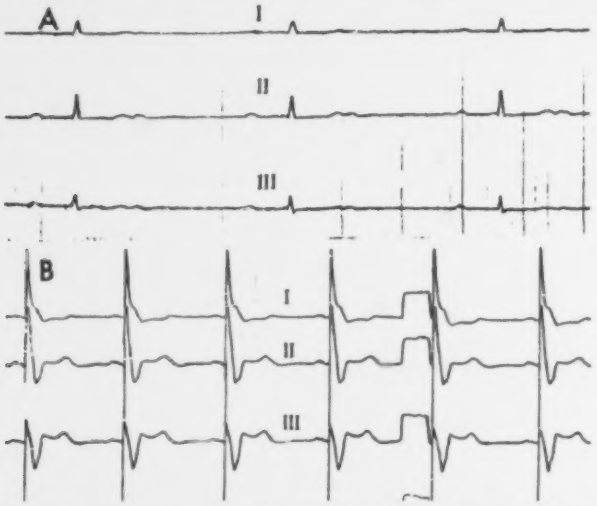


Figure 4. 2:1 A-V block in a 54 year old woman. Before (A) and 2 years after (B) pervenous electrode implantation of atrial-triggered pacemaker.

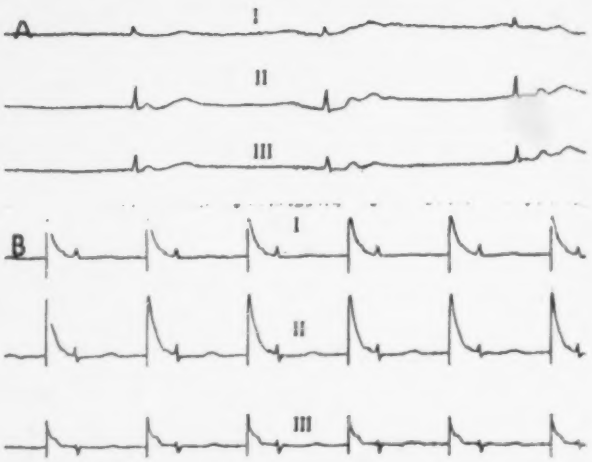


Figure 5. Extreme sinus bradycardia in a 62 year old man. Before (A) and 6 months after (B) pervenous implantation of an anchored atrial electrode coupled to a fixed-rate pacemaker.

An "atrioventricular" delay of 120 msec precedes activation of the output circuit and the production of a stimulating impulse at the ventricular electrode. The pacemakers (Biotronic IVP-44 and IVP-54) used in the procedure are basically designed to provide atrial synchronous operation within a frequency range of 70 to 140 beats/min. Automatic blocks built into the electronic circuit maintain the ventricular rate within this range, thus preventing inadequate or excessive ventricular rates. To this end, each stimulating impulse is followed by a period during which all signals from the amplifier will be suppressed by the timing circuit. This pacemaker refractory period, set at 400 msec, determines the maximal synchronous rate. If the upper limit of 140/min is exceeded, a frequency divider built into the pacemaker circuit provides a properly phased 2:1 ventricular stimulation signal. The maximal rate for a 2:1 block is also limited by the refractory period of the pacemaker, and a shorter refractory period is required if a higher maximal rate is desired. In the event of atrial rates below the lower limit of 70/min, malfunction or fracture of the atrial pickup lead, or arrhythmias such as atrial flutter and fibrillation, the timing circuit provides automatic nonsynchronous ventricular stimuli at 70/min, preventing either block or externally induced "pacemaker tachycardia."

Results

Atrial synchronous systems have so far been implanted by this method in 12 patients (age range 17 to 72 years) with atrioventricular (A-V) block at the Centre of Cardiovascular Research of the Charité Hospital in East Berlin (Fig. 4). In addition, 3 patients with sinoatrial (S-A) block or extreme sinus brachycardia (Fig. 5) were treated by the introduction of an atrial electrode coupled to the output of a fixed-rate pacer system. The follow-up period has been more than 30 months in 2 patients, from 21 to 30 months in 3, from 11 to 20 months in 3, from 6 to 10 months in 4, and from 1 to 5 months in 5. The maximal follow-up period thus far has been 39 months. In no instance was an atrial electrode dislocated.

Transient sensing failure, occasionally evident immediately after implantation, but in all cases corrected after 2 to 5 days, is attributed to traumatic edema or hematoma at the site of implantation. In this series, the long-term performance of these transvenously implanted, anchored atrial electrodes has been faultless.

References

1. **Gilmore JP, Sarnoff SJ, Mitchell JH et al:** Synchronicity of ventricular contraction. Observations comparing haemodynamic effects of atrial and ventricular pacing. Brit Heart J, 25:299-304, 1963
2. **Samet PS, Castillo C, Bernstein WH:** Hemodynamic consequences of atrial and ventricular pacing in subjects with normal hearts. Amer J Cardiol 18:522-525, 1966
3. **Carlens E, Johansson L, Karlof I, et al:** New method for atrial triggered pacemaker treatment without thoracotomy. J Thorac Cardiovasc Surg 50:229-236, 1965
4. **Schaldach M, Bücherl ES, Franke O:** Implantierbare elektrische Schrittmacher zur Langzeittherapie von Reizleitungsstörungen des Herzens Medizinalmarkt. Acta Medico-technica, 15:240-244; 286-288, 1967
5. **Smyth N, Vasarhelyi L, McNamara W, et al:** A permanent transvenous atrial electrode catheter. J Thorac Cardiovasc Surg, 58:773-782; 787-788, 1969
6. **Dodinot BP, Petitier HA, Gilgenkrantz JM, et al:** Clinical experience with atrial-synchronous pacing. Ann NY Acad Sci 167:1038-1054, 1969
7. **Faivre GR, Dodinot BP, Müller J:** Kriterien zur Wahl des Schrittmachers und der Elektroden. Arztl Praxis 81:4270-4273, 1969
8. **Rodewald G, Glebel O, Harms H, et al:** Intravenös-intrakardiale Applikation von vorhofgesteuerten elektrischen Schrittmachern. Z Kreislaufforsch 53:860-866, 1964
9. **Kramer DH, Moss AJ:** Permanent pervenous atrial pacing for treatment of symptomatic sinus bradycardia (abstr). Amer J Cardiol 25:111, 1970
10. **Kastor JA, DeSanctis RW, Harthorne, et al:** Transvenous atrial pacing in treatment of refractory ventricular irritability. Ann Intern Med 66:939-945, 1967
11. **Castillo CA, Berkovits BV, Castellanos A Jr, et al:** Bifocal demand pacing. Chest 59:360-364, 1971
12. **Buck A:** Differentialtherapie mit verschiedenen Herzschrittmachertypen. Verh Deutsch Ges Kreislaufforsch 35: 140-151, 1969

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VENTRICULO-ATRIAL SHUNT

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Fig. 1

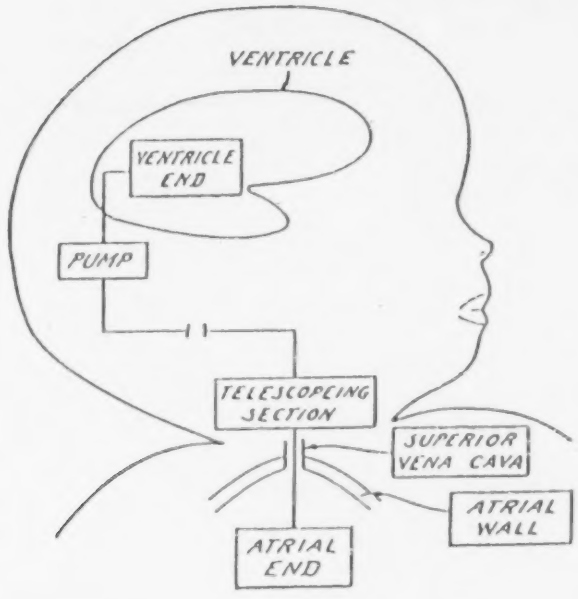


Fig. 2

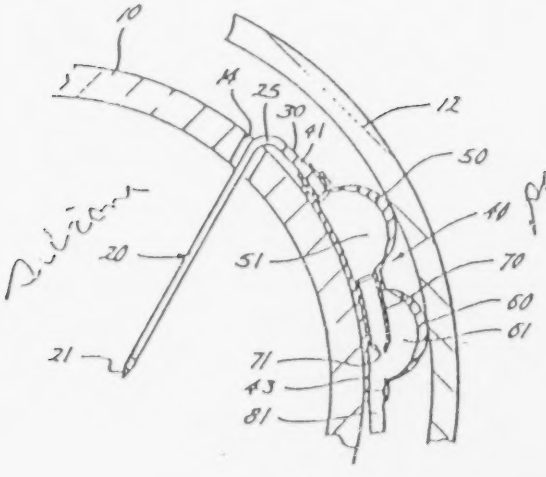
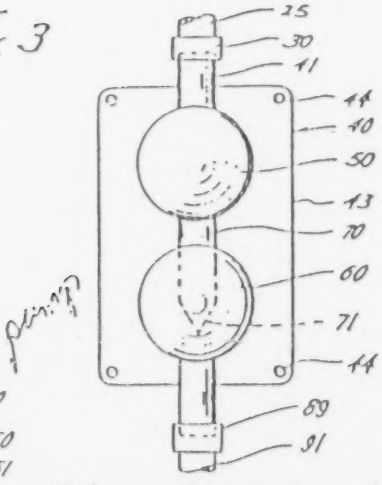


Fig. 3



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VENTRICULO-ATRIAL SHUNT

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Fig. 4

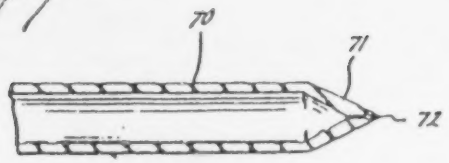
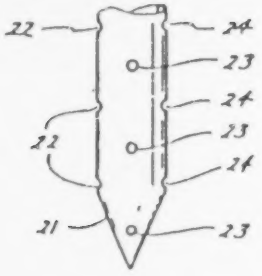


Fig. 5



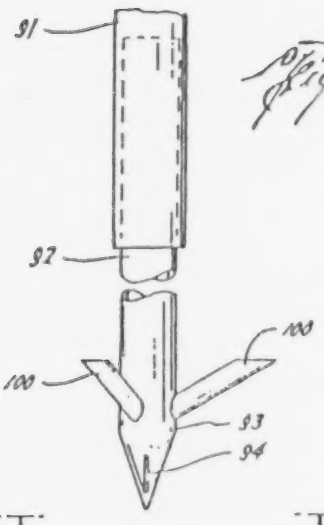


Fig. 6

Fig. 7

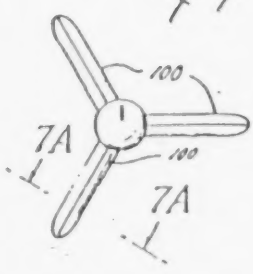


Fig. 7A

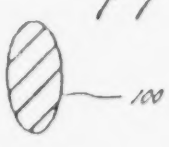
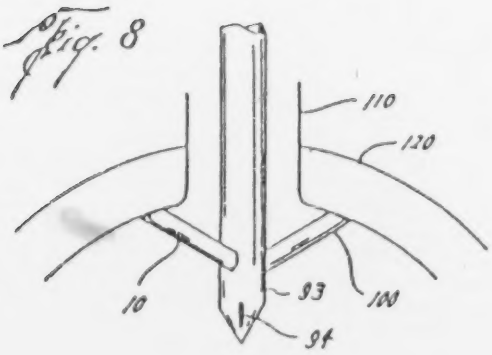


Fig. 8



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United States Patent Office 3,492,996 Patented Feb. 3, 1970

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VENTRICULO-ATRIAL SHUNT

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Filed Feb. 9, 1966, Ser. No. 526,294
Int. Cl. A61m 27/00
U.S. Cl. 128—350 5 Claims

ABSTRACT OF THE DISCLOSURE

This application describes a surgically implantable device for relieving fluid pressure on the brain. The device comprises a ventricular conduit adapted for introduction into the brain, a pumping device attached to the ventricular conduit and an outlet conduit attached to the pumping device and adapted to be inserted into the atrium. The pumping device is a substantially flat, flexible plate adapted to overlie the skull and has a pair of bubble-shaped chambers positioned thereon and adapted for finger manipulation to provide pumping action to clear the conduits of obstructions. The outlet end of the device is provided with flexible wings adapted to hold the device within the atrium or center it in the vein entering the atrium in the event that the end is pulled from the atrium. One-way valves are provided to prevent blood back-flow into the brain.

This invention concerns a new and improved device for treating hydrocephalics, i.e., those persons, usually infants or children being afflicted with, as commonly described, water on the brain. Also, this condition may exist in certain adults whose circulation or absorption of cerebro-spinal fluid is impaired by various inflammatory or tumor processes.

More particularly this invention contemplates a means whereby secreted cerebro-spinal fluid may be directed into the blood stream and thereby throughout the normal course of the body system.

Normally, cerebro-spinal fluid is secreted by the choroid plexus and ventricular lining within the cranial ventricles. Such fluid may enter the vascular system by a route approximated by passing out of the lateral ventricles, through the third ventricle, out the formaina of Magendie and Lushka, into the cisterna magna whenceforth into the subarrachnoid spaces and absorbed by the blood system. Such fluids may be absorbed and recycled several times daily.

With hydro-cephalics the cerebro-spinal fluid is unable to be absorbed adequately. Thus, on continued secretion, pressure increases greatly, causing the ventricles to swell or expand. As expansion occurs the wall material becomes thinned. Expansion occurs at the expense of brain substance, and fluids. Thus, in essence, the head becomes a box, closed save for incoming material.

Previous attempts to relieve the extreme pressures and return such cerebro-spinal fluid to the circulation have been fraught with numerous difficulties. For example, flushing of such earlier devices has proved difficult or frequently impossible, and the cardiac portion has not been permitted to lengthen with normal growth of the patient.

Thus, this invention has as its purpose the permitting of relieving of increased intra-cranial pressure by reintroducing cerebro-spinal fluid into the vascular system.

A further object is the provision of a device which may longitudinally extend so as to permit continuous utilization in a growing human.

Yet another object is the provision of means whereby the ventricular end may be flushed.

These and still other objects and benefits will become

apparent on considering the following appended description and drawings in which:

FIGURE 1 is a schematic representation of the relative positioning of the shunt ventricular and atrial ends, pump and telescoping portions;

FIGURE 2 is a section through a skull showing positioning of the pump mechanism and ventricular shunt relative thereto;

FIGURE 3 is an elevation of the pump mechanisms and connections thereto;

FIGURE 4 is a section through one end of the ventricular-atrial conduit.

FIGURE 5 is an enlarged elevation of the end of the ventricular portion of the shunt;

FIGURE 6 is an elevation of the telescoping portion and atrial end of the shunt;

FIGURE 7 is an end view of the shunt atrial end, taken along lines 6—6 of FIGURE 5, and

FIGURE 7a is a section taken along lines 7a—7a of FIGURE 7; and

FIGURE 8 is a section showing the placement of the shunt atrial end relative to the superior vena cava.

Looking first at FIG. 1, for an overall view of the operation of the device, the venticular end of a shunt device is positioned within a cranial ventricle. Said shunt ventricular end is connected to a pump mechanism, later described, which may be inserted under the scalp. Said pump leads subcutaneously to a telescoping section of a conduit, and thereafter to the atrial end of a shunt, which atrial end is positioned within the atrium of the heart. Said atrial end may be inserted in the jugular vein, through an incision therein, pass therethrough and be prevented from being dislodged from the atrium through or to the superior vena cava by reason of projections near the terminal end of said atrial end.

Look now at FIGURE 2 which depicts the pump and the ventricular portion of the shunt. Said shunt refers to the conduits from either end of the pump. The skull of a person is indicated by the numeral 10, and the scalp by 12. An aperture is shown by 14, which may be a burr hole or even a perforator opening which is substantially smaller.

A ventricular shunt 20, which consists generally of thin flexible hollow conduit, preferably of silicone rubber, has one end 21 inserted within a cranial ventricle, which ventricle is under excessive pressure due to the buildup of cerebro-spinal fluid. Said one end possesses a number of perforations, with the perforations closely bunched and arranged preferably with each grouping being rotated 90° from the adjacent grouping and vertically spaced therefrom, as indicated by groups 22, 23, and 24, respectively (FIG. 5).

The other end 25 may pass through said skull opening 14, to be joined by connector 30, to the ventricular end 41, of pump 40. Said connector may be made of polyethylene, silicone rubber, nylon or other suitable material, and would have an aperture therethrough, communicating both with the ventricular shunt and with conduit-like end 41 of said pump.

The pump 40, actually would perform as a dual pumping mechanism in the following manner. A flexible base portion 43 possesses suture holes 44 for affixing said base to periosteum of skull 10. Spaced toward opposite ends of said base are hemisphere-like bubble portions 50 and 60, which define chambers 51 and 61, respectively, between said bubbles and said base. Actually, said bubbles serve as individual pumps in that each may be compressed so as to eject fluids present within their respective cavities outwardly thereof. Said conduit end 41 is shown to communicate both with ventricular pump 50 and with ventricular shunt 20, by virtue of connector 30. Also, pump 50 communicates with atrial pump 60 by virtue

of ventricular-atrial conduit 70. The atrial end 71 of said conduit terminates within chamber 61 of pump 60. Said atrial end may have a slit 72 formed therein which, in the absence of sufficient pressure against the adjacent walls, would normally be closed. Thus said conduit and slit would function as a one way valve preventing fluids from returning from chamber 61 to chamber 51, i.e., from the atrial shunt through the ventricular shunt thence back into the ventricle.

Atrial pump 60 is linked by conduit 81, by virtue of connector 89, similar to member 30, to the upper member 91 of atrial shunt 90 and communicates therewith by virtue of said conduit, connector and shunt being cylindrically conformed.

Said upper portion 91 will have a larger internal diameter than, and telescopingly receive lower portion 92, both portions consisting of tubing, preferably, again of silicone rubber. The telescoping portion of member 92 may be prevented from sticking by properly coating members 91 and 92.

FIGURES 6, 7, 7a and 8 depict said lower portion of the atrial shunt. The lower or atrial end 93 of member 92, includes one or more slits 94, again functioning as a one-way valve. Positioned closely adjacent thereto are a plurality of slightly upwardly directed, wing-like projections 100. Preferably there are three such projections spaced radially 120 degrees apart around the periphery of the end 93 of the atrial shunt.

It woud be beneficial for the device to be substantially treated with a barium-containing substance so that on X-rays being taken, the exact location of all the parts thereof may be determined.

In actual use, ventricular shunt 20 would be inserted through cranial perforation 14 into a cranial ventricle, the brain being under considerable internal pressure. Cerebrospinal fluid would pass through apertures 22, 23 and 24 into the interior of ventricular shunt 20, therethrough, into cavity 51 of pump 50, thence through conduit 70, out one-way valve 72 into chamber 61 of pump 60. Said pump 60 may, by pressing down on the adjacent scalp, and thereby compressing the pump 60, cause such fluids to pass downwardly through conduit 81, connector 89 and into the upper member 91 of atrial shunt 90, from where it would pass through the atrial end 92 of said atrial shunt, out one-way valve 94, into the atrium from which location said fluids may eventually be absorbed into the blood system. Pressure on pump 50 would normally have the same effect. Normally, in the absence of obstructions or occlusions, said pumps would not need to be utilized, in that said fluids would follow the described route without needing assistance.

Normally the linkage from the pumping mechanism to the atrial end of the atrial shunt may be inserted underneath the skin. The lower member 92 of said atrial shunt 90 would be inserted within the jugular vein and course through the superior vena cava, pass downwardly therethrough into the atrium. By virtue of projections 100, which may readily bend upwardly, so as to permit downward passage through said superior vena cava 110, said atrial end of said atrial shunt, may not return upwardly through vein 110, in that said projections 100 would rest adjacent atrial wall 120. This would tend to prevent scarring of the superior vena cava wall as well as thrombosis which might occur should member 92 be pulled back within vein 110, and be bound to the wall thereof by a membrane or clot. Even should said atrial end be pulled back within vein 110, said projections 100 would keep said atrial end centered in the stream of blood flowing through said vein, keeping the device operative. Positioning of atrial end 93 is permitted, even in growing children by virtue of the telescoping nature of members 91 and 92.

A further advantage permitted by this device is the flushing of the ventricular end of the shunt. Inasmuch as conduit 70 has a one-way valve 72 at one end, if pump 60 is depressed so as to close said valve, then pressure on valve 50 will tend to force fluids contained in cavity 51 and the ventricular shunt 20 back through the perforations in end 21. Thus, stoppages resulting from occlusion of the ventricular end, perhaps bits of brain matter, debris or clumped leukocytes may be overcome.

Although only a single embodiment of this invention has been described it should be apparent that numerous modifications would be possible by one skilled in the art without departing from the spirit of the invention. The scope of which is intended to be limited only by the following appended claims.

What is claimed is:

1. In a surgically implantable device for relieving excess pressure within the brain comprising a first fluid conduit means adapted for introduction of at least a portion thereof into a brain ventricle, a second fluid conduit means for fluid outlet, a pumping device positioned between said first and second conduit means and interconnecting the same, and a one-way valve positioned in the system to prevent fluid back-flow into the brain, the improvement which comprises:

said pumping device comprising a pair of hemisphere-like, bubble-shaped, thin-walled resilient chamber portions positioned in spaced relationship on a substantially flat, flexible base member, said base member defining the lower boundary of each of said chamber portions, each portion being adjacent to one of said conduits and intercommunicating therewith,

said bubble-shaped chamber portions being interconnected by third conduit means including a one-way valve whereby when said pumping device is manipulated, the first conduit can be flushed to clear it of obstructions.

2. The improvement as defined in claim 1 wherein said third conduit means terminates within said chamber adjacent to said second conduit means.

3. The improvement as defined in claim 2 wherein said one-way valve in said third conduit means is provided with a slit which acts as a one-way valve.

4. The improvement as defined in claim 1 wherein: the terminal portion of said second conduit means, which is opposite the end to which said pumping device is connected, is provided with a plurality of wing-like, flexible projections adapted to rest against blood vessel walls of the patient and center the conduit in the flow of the blood.

5. The improvement as defined in claim 1 wherein: said flexible base member is provided with means for attachment of sutures thereto.

References Cited

UNITED STATES PATENTS

2,616,429	11/1952	Merenlender	128—350
2,969,066	1/1961	Holter et al.	128—350
3,020,913	2/1962	Heyer	128—350
3,111,125	11/1963	Schulte	128—350
3,108,595	10/1963	Overment	128—350
3,233,610	2/1966	Wade	128—350
3,288,142	11/1966	Hakim	128—350

OTHER REFERENCES

Lancet: vol. 2 (63), No. 7315, Nov. 9, 1963, pp. 983–984.

Rickham: Brit. Med. Jour., July 1964, p. 173.

Hakim - Valve System for Ventriculo-Atriostomy, Cords Corp. Publication dated Oct. 5, 1965, pp. 3 and 6–8 relied on.

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United States Patent

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[11] 3,635,223

[45] Jan. 18, 1972

[54] EMBOLECTOMY CATHETER

[72] Inventor: Charles H. Kliernan, Brooklyn, N.Y.

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[22] Filed: Dec. 2, 1969

[21] Appl. No.: 881,363

[52] U.S. Cl. 128/348, 128/356

[51] Int. Cl. A61m 25/00, A61b 17/22

[58] Field of Search ..... 128/348-351, 344, 128/303, 325, 246, DIG. 9, 2, 356, 328

[56] References Cited

UNITED STATES PATENTS

2,701,559	2/1955	Cooper	128/2
3,467,101	9/1969	Fogarty et al.	128/348
2,024,982	12/1935	Scott	128/349 X
2,856,934	10/1958	Petillo	128/349 X
2,648,329	9/1954	Wallace	128/349
2,780,787	4/1957	Trace	128/303
3,308,819	3/1967	Arp	128/215
3,416,531	12/1968	Edwards	128/348

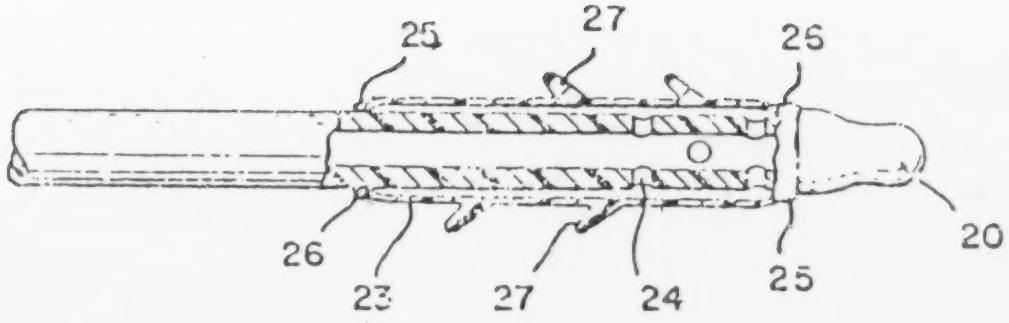
Primary Examiner—Dalton L. Truluck

Attorney—W. Saxton Seward

[57] ABSTRACT

Apparatus for extracting emboli comprising a cannula, preferably guidable, adapted to be projected through a body passage (e.g., vein or artery) to a point adjacent the embolus to be removed, together with a catheter adapted to be passed through the cannula and having a distal end provided with an inflatable balloon the surface of which has rearwardly angled protrusions designed to engage an embolus into which the catheter end has been projected and to convey the captured embolus into the cannula as the catheter is withdrawn therein

7 Claims, 7 Drawing Figures



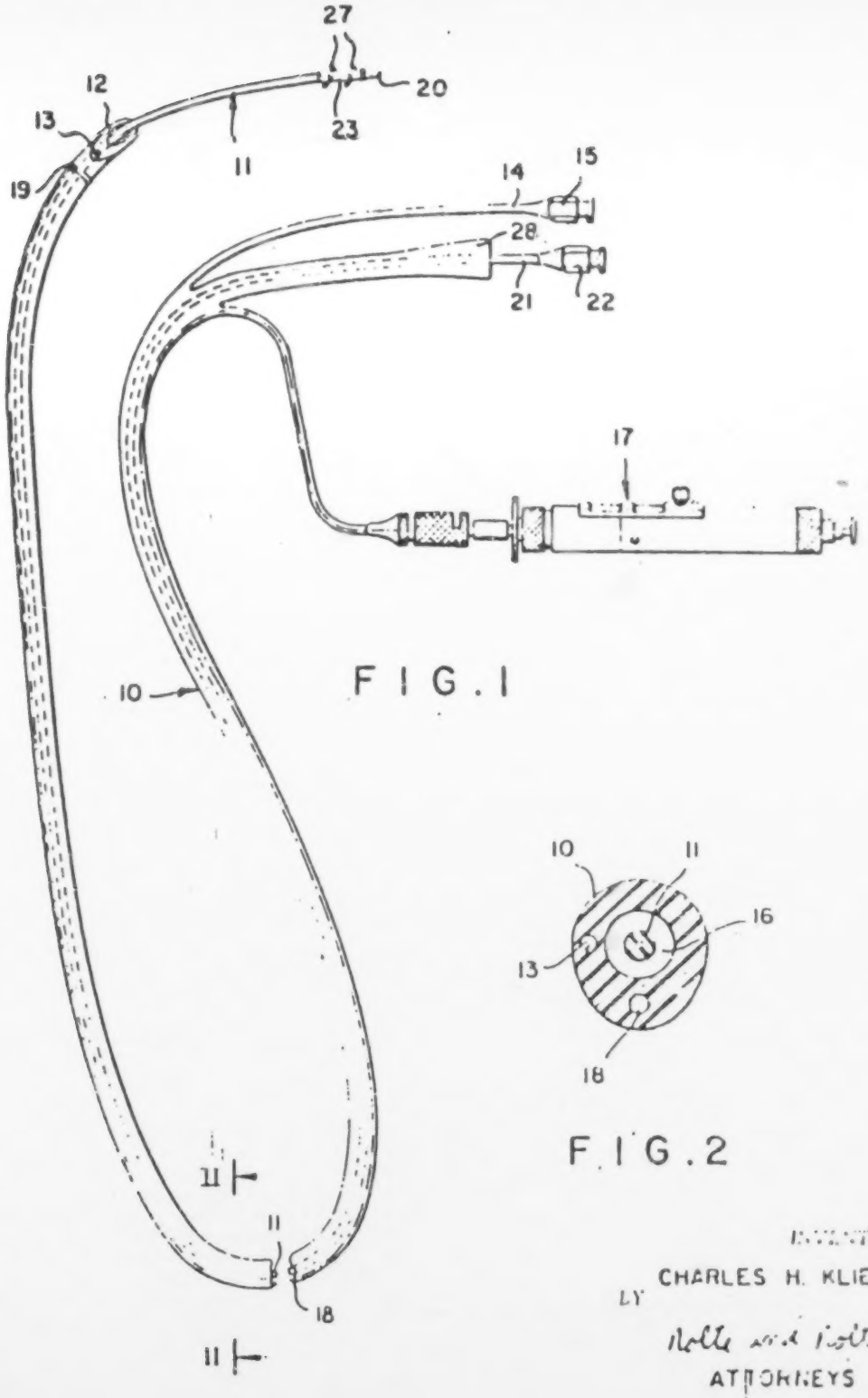


FIG. 1

FIG. 2

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FIG. 3

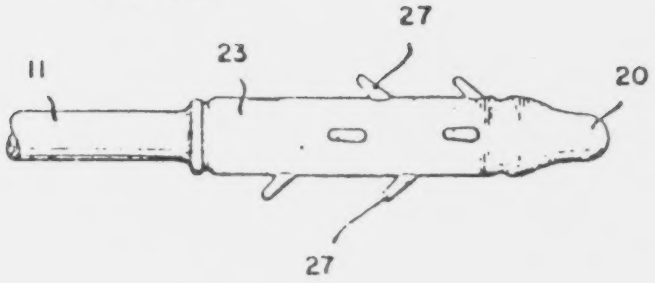


FIG. 4

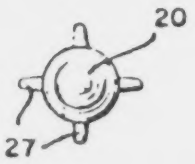


FIG. 5

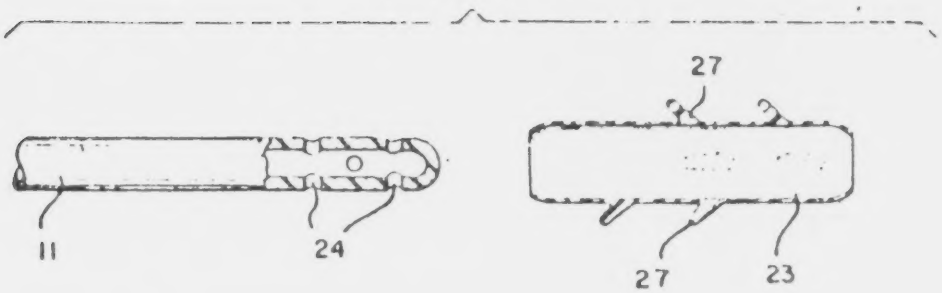


FIG. 6

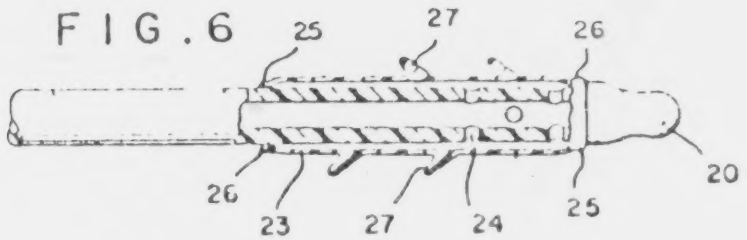




FIG. 7

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EMBOLECTOMY CATHETER

BACKGROUND OF THE INVENTION

A definite need exists for a catheter unit to remove pulmonary emboli. A pulmonary embolus is a blood clot that has formed in some area of the body and traveled via the venous system into the pulmonary arteries. The site of origin of these emboli is usually the veins of the leg, secondary to conditions such as thrombophlebitis. If a massive pulmonary embolus occurs, the mortality rate is high. The only method available at this time to remove these clots is by a direct surgical attack on the pulmonary artery. Even then the mortality rate is very high. The present catheter unit's purpose is to avoid the need for surgery and permit the emboli to be removed via a peripheral vein such as the femoral vein. Other uses have been developed for one or both parts of the catheter unit to be described. Each use will be described in detail.

A practical embodiment of the invention is shown in the accompanying drawing wherein:

FIG. 1 represents an elevation of the outer guided cannula with the extraction catheter inserted therethrough, parts being broken away;

FIG. 2 represents a cross section on the line II—II of FIG. 1;

FIG. 3 represents an elevation of the distal tip of the extraction catheter on an enlarged scale;

FIG. 4 represents an end view of the tip shown in FIG. 3;

FIG. 5 represents detailed axial sections of the catheter, adjacent its distal tip, and of the balloon prior to assembly thereof;

FIG. 6 represents the same parts as in FIG. 5, assembled; and

FIG. 7 represents an elevation of a mandrel on which the balloon may conveniently be formed.

Referring to the drawings, the apparatus is shown as comprising two parts, the outer guided cannula 10 and the inner catheter 11, constituting the emboli-extracting instrument.

The outer cannula 10, which may be 80 cm. to 100 cm. in length, is preferably 20 F. in diameter with a substantially circular lumen having a diameter on the order of 0.164 inch, its distal end 12 being opened at an angle to provide an actual opening larger than the lumen. The cannula 10 is formed with a main lumen 16 and a small second lumen 13, open at the distal end (e.g., in the short end of the bevel) and provided at its tubular proximal end 14 with a fitting 15, to receive a syringe tip for the injection of dye, for instance. The cannula 10 is flared proximally, as indicated at 28, to permit insertion of the catheter 11, as described below; it is also provided with a deflecting device comprising the operating handle 17 and a fine wire 18 secured at its distal end 19 near the distal end 12 of the cannula, by which means said cannula end can be deflected, in a known manner, and guided to desired locations. The handle 17 may be of the type shown in Muller U.S. Pat. No. 3,425,740, or an adaptation thereof. The material of the cannula 10 is suitably a radiopaque polyvinyl chloride or equivalent nonreactive, nontoxic and atraumatic material, with or without wire reinforcement.

The inner catheter 11, 20 cm. to 25 cm. longer than the cannula 10 may be 3 F. to 8 F. in diameter, radiopaque and of woven Dacron or the like. Its distal tip 20 is soft, flexible and closed, and its proximal end 21 is provided with a fitting 22 to receive tip of a syringe for a purpose described below. The catheter 11 has an inflatable balloon 23 of latex, vinyl or other suitable elastomeric material mounted adjacent its distal tip, the balloon being constituted by a substantially cylindrical sleeve long enough to cover the openings 24 normally provided near the tip of such a catheter, the ends of the sleeve being tied by threads 25 and tightly secured to the surface of the catheter by said threads and by an application of a suitable adhesive 26 over the threads and adjacent edges of the sleeve.

The balloon is provided with a plurality of integrally formed "barbs" or protrusions 27, each approximately 1 mm. in length, slanted away from the tip of the catheter at angles of 30° to 60°, for instance (45° being shown), and distributed around the balloon surface at intervals preferably no greater than 90° with respect to the catheter axis. The diameter of the balloon portion, including protrusions 27, should be not appreciably greater than the inside diameter of the cannula (e.g., less than 0.164 inch) with the balloon collapsed (not inflated), to enable said portion to be passed through the cannula, as described below, without undue frictional resistance.

In using the apparatus for pulmonary embolectomy, the emboli-extracting catheter 11 is placed within the outer cannula 10, the unit is introduced into the femoral vein, and under observation with an image intensifier, is guided up through the vena cava, through the right side of the heart and out into the pulmonary artery. Dye is then injected to determine the exact location of the embolus, so that the distal end of the cannula 10 may be placed close to it. The inner catheter 11 is pushed through and past the clot, (e.g., to a position as shown in FIG. 1 with respect to the cannula 10) and then pulled back, the protrusions 27 engaging the clot and ensuring its capture and withdrawal into the cannula through the enlarged opening at the end 12. If necessary, due to the size of the vein and/or clot, the balloon 23 may be inflated by means of a syringe engaged in the fitting 22, the vinyl balloon having sufficient elasticity to permit an appreciable increase in its effective diameter. Following the first withdrawal of the catheter into the cannula, dye is again injected to determine if all the clot has been removed, and repeated projections and retractions of the catheter can be made until the clot removal is completed. The slanting arrangement of the protrusions 27 ensures that they will engage the clot only for withdrawal, emerging from the cannula relatively "clean" for each repeated pass, if more than one pass is needed. When the clot appears to have been completely captured, the entire unit is removed.

It has been found that, in many instances, the presently used Fogarty catheter is not fully effective to remove iliofemoral venous or arterial emboli. The inner emboli-extracting catheter 11 can be used (without the cannula 10) for this purpose. Its advantages reside in the soft flexible tip, the vinyl balloon with slanted protrusions, and its ability to remove clots without necessarily having to inflate the balloon in the vessel. In such an operation the catheter is introduced distally into the femoral artery or vein and advanced past the embolus, the soft flexible tip ensuring that the vessel wall will not be damaged. After the balloon has been pushed past the clot, it is withdrawn, the protrusions 27 engaging the clot and removing it. If necessary, the balloon may be inflated to the desired extent to ensure engagement with and removal of the clot. Repeated passes may be made into the femoral, deep femoral, popliteal and iliac vessels to completely remove the clot or clots. The protrusions on the balloon are rounded and sufficiently flexible to avoid damage to the vessel but are firm enough to hold onto the clot. When using the catheter 11 without the cannula 10 it is particularly convenient and desirable for the catheter to be calibrated at suitable intervals such as every 10 cm.

Instances have been reported of occlusion of the renal artery by emboli, and the only presently known procedure for saving the affected kidney is operating on the patient to remove the clot. The cannula and catheter described herein can be used to remove such clots, thus avoiding the need for surgery. In this situation, the assembled unit is passed up the femoral artery to the level of the renal artery, as located by the injection of dye. The slant-opened distal tip 21 of the cannula is approximated to the opening of the renal artery and the inner catheter 11 is then projected into the renal artery to pass, engage and remove the clot or clots as described above. The clot or clots captured with the cannula are then removed as the cannula is withdrawn.

A convenient and economical means for making the balloon 23 is illustrated in FIG. 7, where the metal (e.g., brass) mandrel 30 is shown as having a handle 31, a shank 32 and a cylindrical enlarged portion 33 tapering smoothly at both ends to the diameter of the handle, as indicated at 34. A plurality of slanting tapering holes 35 are drilled at suitable points, cor-

responding to the desired number and distribution of the projections 27. The mandrel is used by dipping in a bath of elastomeric material, maintained sufficiently liquid to flow into the holes 33, the material depositing on the mandrel to the desired thickness. After removal from the bath, the deposited material is cured in an appropriate manner, the sleeve with "barbs" on its inner surface is turned inside out, and the ends trimmed to leave a balloon as shown at the right of FIG. 5. The inside diameter of the cylindrical portion of the balloon may conveniently be slightly greater than the outside diameter of the catheter, as indicated in FIG. 6, the actual difference being on the order of 0.010 to 0.020 inch.

As used herein, "distal" refers to the leading end or direction of advancement into the body and "proximal" refers to the end or direction opposite to said distal end or direction.

What is claimed is:

1. An embolectomy catheter comprising an elongated tubular body having a closed soft flexible distal tip, at least one perforation through the wall of said tubular body adjacent said tip, inflatable sleeve of elastomeric material covering said perforation and sealed to the surface of said body distally and proximally of said perforation, and a plurality of protrusions of the same material integrally formed on said sleeve at a plurality of circumferential points, projecting laterally therefrom and slanted away from said distal tip, whereby when said tip is inserted within a blood vessel past an embolus, said slanted protrusions will engage said embolus and upon retraction of said catheter will ensure withdrawal of said embolus from the blood vessel.

2. A catheter according to claim 1 which includes a fitting on the proximal end of said body adapted to receive a syringe tip.

3. A catheter according to claim 1 in which the catheter is of a woven plastic material having dimensional stability and being at least partially radiopaque.

4. A catheter according to claim 1, in which the sleeve is sealed to the body by a circumferential tie covered by adhesive.

5. In combination, a catheter according to claim 1 and an outer cannula having at least one lumen open at both ends, the diameter of said lumen being substantially as great as the diameter of a circle passing through the outer ends of said protrusions, the length of said cannula being less than the length of the catheter, and said catheter being slidably received within in said cannula.

6. The combination of claim 5 in which the distal end of the cannula has a slanted opening, the area of which is larger than the cross-sectional area of the cannula lumen.

7. The combination of claim 5 in which the cannula is a radiopaque vinyl plastic and the catheter is at least partially radiopaque.

* * * * *

United States Patent [19]

Collett

[11] **3,717,151**

[45] **Feb. 20, 1973**

[54] FLESH PENETRATING APPARATUS

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[22] Filed: March 11, 1971

[21] Appl. No.: 123,291

[52] U.S. Cl. 128/347, 128/350

[51] Int. Cl. A61b 17/34, A61m 27/00

[58] Field of Search ..... 128/242, 244, 343, 345, 347, 128/348, 350 R, 350 V, 351

[56] References Cited

UNITED STATES PATENTS

653,013	7/1900	Armour	128/244
668,879	2/1901	Miller	128/343
2,779,335	1/1957	Hausser	128/347
3,039,468	6/1962	Price	128/347
3,241,554	3/1966	Coanda	128/345 X
3,630,192	12/1971	Jamshidi	128/347 X

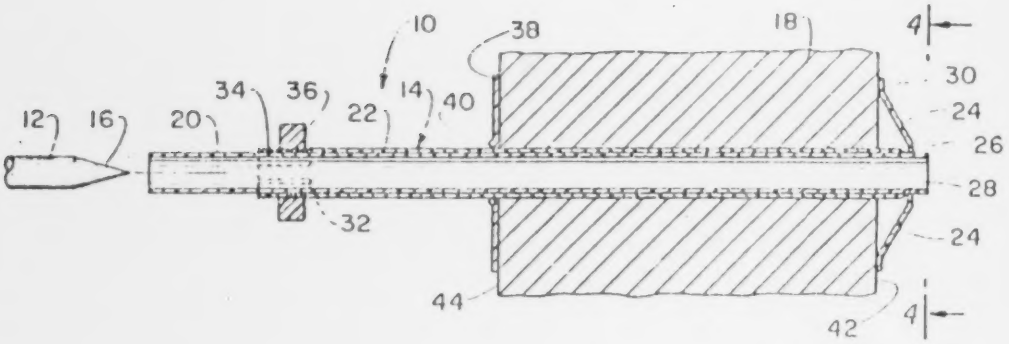
Primary Examiner—Channing L. Pace

Attorney—Robert E. Geauque

[57] ABSTRACT

A catheter apparatus for retention within the body of an animal employing a sleeve assembly composed of an inner sleeve telescopingly supported within an outer sleeve, a multiple radially expandable finger assembly hingedly integrally connected at one end to the outer sleeve and capable of being maintained in the radially outermost position by the inner sleeve, the fingers being movable substantially in line with the outer sleeve upon disassociation of the inner sleeve.

8 Claims, 6 Drawing Figures



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FLESH PENETRATING APPARATUS

BACKGROUND OF THE INVENTION

The field of this invention relates to medical devices and more particularly to a device which provides access to an interior cavity of an animal body.

In a certain area of medicine trocars are readily employed. A trocar is a sharp pointed instrument which is used to insert a cannula into a body cavity to be employed as a drainage outlet. Basically, a cannula is an elongated rigid tubular element which is to provide communication exteriorally of the body to within a cavity of the body. For example, cannulas are frequently used upon cattle to vent an animal's stomach upon it becoming bloated. Such a disease is quite common in cattle and if a vent is not provided, frequently the animal dies. Additionally, a passage which is provided by a cannula can be employed to facilitate direct insertion of medication into the stomach cavity of an animal. Further, such devices may be applied to an infected wound which requires drainage.

Although such devices are most frequently used upon the lower order of animals, there are certain instances in which a trocar and cannula can be applied to humans. The use of such an instrument in humans would be primarily toward the application of medicines within an internal cavity, such as the stomach, or to effect drainage of an infected wound.

Trocars and cannulas may be made in numerous sizes. To effect drainage of a wound a needle-like size may be adequate. However, to effect insertion of such into the stomach cavity, a pencil size (or larger) cannula may be desired. Heretofore, the trocar related to a pointed instrument which is slidably contained within the cannula. The trocar is caused to penetrate the flesh of the animal and to extend a desired depth within the animal. The trocar carries along with it the cannula. Upon the cannula reaching the desired depth, the trocar is removed leaving an open passage to the particular desired cavity within the animal. In most instances, it is desirable to leave the cannula in position for a period of time of several days. In the lower order of animals, it has not been uncommon for such located cannulas to be dislodged from position either falling exteriorly of the body or being caused to move interiorly of the body as into the stomach cavity. In the past, in an effort to prevent cannulas from moving into the stomach cavity, a portion of the cannula is enlarged and is to extend exteriorly of the body, thereby preventing such dislodgment from occurring. However, no means is provided to prevent dislodgment of the device exteriorly of the body.

In the past, trocars have been made of a stainless steel material of extremely high precision. As a result, such devices have proved most expensive, thereby making it a significant item of purchase for the veterinarian or medical doctor.

It would be desirable to design a trocar and cannula which facilitated entrance of the device interiorly of the body, such device absolutely precluding accidental dislodgment of the device once in position, and such a device being constructed simply and of a low-cost material of construction.

SUMMARY OF THE INVENTION

The apparatus of this invention may provide for the employment of a trocar which is slidably movable within a first sleeve. The trocar can be formed of either a rigid plastic or a rigid metal material with one end thereof being pointed. Basically, the trocar will be of cylindrical configuration. However, polygonal shaped configurations are not to be precluded. A second sleeve is to be located about the first sleeve which is to be of a shorter elongated length than the first sleeve. A combination of the first sleeve and the second sleeve form what is frequently called the cannula. The end of the second sleeve which is to be located within the cavity of the animal includes a plurality of radially extendable fingers. The fingers are hingedly pivoted with respect to the first sleeve and are caused to come in contact with the first sleeve upon being extended substantially at a right angle with respect to the sleeve axis. Adjacent the opposite end of the second sleeve and mounted thereupon for a sliding movement is an annular collar. The annular collar is capable of unhindered movement toward the fingers but incurs hindered movement away from the fingers. The end of the second sleeve which is to extend exteriorly of the body is externally threaded and is adapted to cooperate with a nut. This end of the second sleeve is also longitudinally slit a small amount with a plurality of equiangularly spaced apart slits. This end of the second sleeve is also tapered slightly so that upon moving a nut along the second sleeve toward the collar effects contraction of the slits and thereby a binding action to non-removably secure the second sleeve to the first sleeve. Upon the nut being moved directly adjacent the end of the second sleeve, the first sleeve is movable with respect to the second sleeve. Upon sufficient extraction of the first sleeve with respect to the second sleeve, the fingers rotate approximately 90° into substantial longitudinal alignment with the axis of the first sleeve. As a result, no tissue damage occurs during removal of the device due to the fingers being extended. The cannula may be employed without a trocar by inserting the cannula through an existing opening into a cavity. Existing openings may comprise the mouth, nose, ear, or the like. Also, existing openings may also be previous openings formed by a trocar. Further, the cannula may be inserted by a trocar which surrounds the cannula such as a hypodermic needle.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a longitudinal cross-sectional view of the apparatus of this invention showing the trocar and combined cannula during partial insertion through the tissue of an animal;

FIG. 2 is a cross-sectional view of the apparatus of FIG. 1 taken along line 2—2 of FIG. 1;

FIG. 3 is a cross-sectional view similar to FIG. 1 but showing the cannula in the retained position with the trocar being removed therefrom;

FIG. 4 is an end view of the cannula arrangement of this invention taken along line 4—4 of FIG. 3;

FIG. 5 is a fragmentary cross-sectional view showing the fingers mounted upon the second sleeve in the retracted position to facilitate removal of the cannula from the tissue; and

FIG. 6 is a view similar to FIG. 5 showing the cannula during partial removal through the tissue.

DETAILED DESCRIPTION OF THE SHOWN EMBODIMENT

Referring particularly to the drawing, there is shown in FIG. 1 the apparatus 10 of this invention broadly including a trocar 12 and a cannula assembly 14. The trocar 12 is in the general configuration of a cylindrical rod which has the pointed end 16. It is to be understood that the trocar can be made extremely small resembling a needle or can be much larger as in the shape of a pencil or the like. It is also to be understood that the trocar 12 can be in other cross-sectional configurations such as square or rectangular shape. It happens to be that the cylindrical shape depicted would be the easiest to manufacture and also would be the easiest to be inserted through the tissue 18 of the animal with minimum damage.

The trocar 12 is slidably mounted in a snug fitting manner within the first sleeve 20 of the cannula assembly 14. Telescopingly mounted about the first sleeve 20 is a second sleeve 22. Both the first sleeve 20 and the second sleeve 22 are to normally be manufactured from the same material of construction as a rigid plastic or other similar material. Also, the trocar 12 can be either a plastic or metallic material. The second sleeve 22 is of a shorter length than the first sleeve 20. The reason for the difference in length will become readily apparent further on in this specification.

Secured to one end of the second sleeve 22 is a plurality of fingers 24. Each of the fingers 24 is to be formed of a plastic material similar to the material of construction of the second sleeve 22. Each of the fingers 24 is readily disposed with respect to the second sleeve 22. It is to be noted that the number of fingers 24 is to be strictly a matter of choice or design; however, it has been found that eight in number proves to be most satisfactory.

The base of each of the fingers 24 is connected by means of a plastic hinge 26 to the second sleeve 22. Each of the plastic hinges 26 forms an integral connection with the second sleeve 22 and with its respective finger 24. The plastic hinge 26 permits pivotal movement of over 180° from the position shown in FIG. 1 of the drawing to the position shown in FIG. 6 of the drawing. Each of the fingers 24 includes a shoulder 28 adjacent the plastic hinge 26. The function of the shoulder 28 is to be described further on in this specification. Each of the fingers 24 includes a flattened foot-like area 30 adjacent its extremity. The function of the flattened area will also be described further on in this specification.

At the other end of the second sleeve 22 are located a plurality of equiangularly spaced apart longitudinal slits 32. The second sleeve 22 in the area adjacent the slits 32 is exteriorly threaded at 34. A nut 36 is adapted to cooperate with the threads 34 and be movable longitudinally upon the second sleeve 22. The second sleeve 22 in the area of the threads 34 is of a steadily increasingly circumference from the end of the second sleeve 22 to the termination of the slits 32. As a result, by tightening nut 36, a concentric contraction of the second sleeve 22 results which effects a binding action upon the first sleeve 20. This binding action is sufficient to firmly retain the second sleeve 22 together with the first sleeve 20.

Located about the second sleeve 22 nearer the nut 36 than the fingers 24 is an annular collar 38. The collar 38 is crimped at 40 in the aft direction with respect to the fingers 24. The function of the crimping 40 will also be explained further on in this specification. It is to be noted that the collar 38 is slidable about the second sleeve 22 which will also be explained in the following operation of the invention.

The operation of the apparatus 10 of this invention is as follows: It will be presumed that an animal such as a cow has become bloated in the stomach and the gas within the animal's stomach must be vented to the ambient. The veterinarian then locates the first sleeve 20 beyond the fingers 24 which are secured to the second sleeve 22. The operator then tightens nut 36 securing the sleeve 20 and 22 in this arrangement. The fingers 24 are located adjacent the exterior surface of the second sleeve 24. The trocar 12 is then inserted within the first sleeve 20. The operator then places the pointed end 16 adjacent the outer skin of the animal in the particular desired location. The operator then impacts the aft end of the trocar 12 causing the trocar 12 to penetrate the tissue 18. It is upon the penetration of the trocar 12 is to the desired depth, as in this instance to within the stomach cavity, the cannula 14 is likewise to pass through the tissue 18 until the fingers 24 entirely extend within the cavity. The operator then removes the trocar 12 providing a vent opening from the ambient to the stomach cavity by means of the passage within the first sleeve 20. The operator then grasps the exterior portion of the cannula assembly 14 and exerts a force thereupon tending to draw such from the animal. As a result, the free ends of each of the fingers 24 come into contact with the stomach wall 42 and are caused to pivot substantially 90° until the flattened areas 30 are in an abutting relationship with the wall 42. The shoulder 28 of each of the fingers 24 comes into abutting contact with the first sleeve 20 thereby preventing further pivotal movement of the fingers 24 past the 90° position. The operator can feel when this occurs because further outward movement of the assembly 14 is vigorously resisted.

The operator then moves the collar 38 along the second sleeve 22 until the collar comes into an abutting contactual relationship with the outer surface 44 of the skin of the animal. The collar 38 is then moved an additionally small amount tending to compress the tissue 18 between the collar 38 and the fingers 24. As a result, a binding action occurs between the fingers 24 and the collar 38 tending to force the crimped portion 40 into greater frictional engagement with the second sleeve 22. As a result of the foregoing, the apparatus 10 of this invention has been installed within the tissue of an animal and is to be firmly retained therein and not capable of being accidentally dislodged. Not only has a vent been provided within the stomach cavity but also a passage is provided for the direct application of medicine or other compounds.

It is to be understood that it is not necessary for the device to be inserted within an open cavity such as a stomach cavity. The apparatus could be inserted within a wound which has become infected. Upon being inserted the desired depth, the pull-back motion upon the

cannula assembly 14 would merely cause the fingers 24 to extend within the adjoining tissue. This extension of the fingers 24 will not be sufficient as to cause significant damage to the tissue. In this instance the drainage for the infected area of the wound would be provided as well as a means to apply a medication directly to the infected area.

To effect easy removal of the apparatus 10 of this invention the procedure is as follows: The operator loosens nut 36 until the first sleeve 20 can be moved relative to the second sleeve 22. Movement of the first sleeve 20 with respect to the second sleeve 22 is accomplished until the forward end of the first sleeve 20 is moved sufficiently to no longer be in cooperation with the shoulder 28 of the fingers 24. As a result, the fingers 24 are free to pivot with respect to the second sleeve 22 to the position in substantial alignment with the longitudinal axis of the second sleeve 22. Thereby as the second sleeve 22 is withdrawn from the tissue 18, the fingers 24 do not hinder the withdrawing movement.

Prior to reusage of the apparatus 10 of this invention, the fingers will be manually pivoted up against the tube 22 as shown in FIG. 1 of the drawing. Also, prior to reusage, the collar 38 is to be manually moved adjacent the threaded area 38. Movement of the collar 38 is not difficult in this direction when there is no force causing the crimped portion 40 to dig into the second sleeve 22. At this time, the apparatus 10 of this invention is ready to be reused.

Another primary advantage of the apparatus of this invention is that the cannula assembly may be employed without the use of the trocar 12. The cannula assembly 14 will be operated in a manner similar to the above described operation. However, the collar 38 may not be employed if the cannula assembly 14 is conducted a substantial distance through a natural cavity as the mouth or through a blood vessel. Actually, it is envisioned that the cannula assembly 14 may be conducted through a blood vessel and lodged in place within the heart. In such instances the inner sleeve 20 may be extended to a substantial length as well as the outer sleeve 22.

Another use contemplated for the apparatus 10 of this invention is that various measurements could be taken by liquid gauges located within the passage of the first sleeve 20. Also, each of the fingers about the flattened areas 30 could have overlapping flaps to protect the tissue in the cavity around the insertion hole. Since the cannula assembly 14 is to be made of a plastic material, it is to have no chemical reaction to tissue. Also, the cannula assembly 14 need not be constructed entirely rigid. The center portion of the cannula assembly may be flexible to facilitate curved movement of the cannula assembly 14 through a body passage (such as a blood vessel). It is only necessary for the ends of the cannula assembly to be rigid to effect operation of the fingers 24 and the nut 36. Basically the uses of the apparatus 10 of this invention are unlimited and up to the ingenuity of the operator.

I claim:

1. A catheter apparatus adapted to be inserted interiorly of an animal body, said apparatus comprising:

a first sleeve and a second sleeve, said second sleeve slidably mounted upon said first sleeve, the combined said sleeves having an inner end and an outer end, said inner end adapted to be inserted into the animal body;

a plurality of separate fingers attached to said inner end of said second sleeve, the base of each of said fingers being pivotally connected to said second sleeve, a shoulder located upon each of said fingers at its said base;

each of said finger elements being movable between a first position and a second position and a third position, the fingers in said first position being in an exterior abutting relationship and in substantial alignment with said second sleeve, said first position being the normal position of said fingers during the insertion movement of said apparatus within the animal body, said second position being such that each of said fingers is substantially perpendicular to the longitudinal axis of said second sleeve said third position being such that said fingers extend beyond said second sleeve and in substantial alignment with said axis, the shoulders being in contact with said first sleeve when the fingers are in said second position, thereby being prevented from movement toward said third position, whereby said fingers may be moved into said third position when said first sleeve is displaced interiorly of said second sleeve so that said shoulders are no longer in abutting contact with said first sleeve, whereby said fingers substantially unhinder withdrawal movement of said apparatus from said animal body.

2. The apparatus as defined in claim 1 including:

the outer extremity of each of said fingers being inclined, the inclination being such that with said fingers in said first position, said outer extremity being inclined outwardly away from said second sleeve, thereby during insertion movement of said apparatus within an animal body said inclined portion of said fingers substantially unhinder insertion movement, and upon said apparatus being completely inserted within the animal body slight movement in reverse to the insertion movement causes said inclined portions of said fingers to contact the animal body and forcibly pivot said fingers to said second position.

3. The apparatus as defined in claim 1 wherein:

each of said fingers is equiangularly spaced from each other about said second sleeve.

4. The apparatus as defined in claim 3 wherein:

each of said fingers is integrally connected to said second sleeve through a plastic hinge.

5. The apparatus as defined in claim 1 wherein:

first means adjustably located upon said second sleeve adjacent said outer end, with said fingers in said second position said first means to contact the exterior surface of the animal body to thereby effect a squeezing of the tissue of the animal between said first means and said finger assembly.

6. The apparatus as defined in claim 5 wherein:

said first means comprises a collar slidably mounted upon said second sleeve.

7. The apparatus as defined in claim 1 wherein:

said first sleeve is of a greater longitudinal length than said second sleeve.

8. The apparatus as defined in claim 1 wherein:

securing means is connected between said first sleeve and said second sleeve to fixedly retain the position of said sleeves in respect to each other.

* * * * *

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4 MONTH IN VIVO
6950 TINED ENDOCARDIAL
VENTRICULAR LEAD STUDY

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DEFENDANT'S EXHIBIT
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NO.

DAIG EXH.
Plaintiffs Exhibit 28
Government's
Defendants Date: 1/11/83

Case No. 4-79-256 and
4-80-611

Deputy Clerk

6950 TINED ENDOCARDIAL VENTRICULAR LEAD

ANIMAL RESEARCH PERFORMANCE

FINAL REPORT

PATENTS CONFIDENTIAL

MARCH 1977

PHYSIOLOGICAL RESEARCH LABORATORY

MEDTRONIC, INC.

6950 Tined Endocardial Ventricular Lead System (Version G)

Final Report
March 1977

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ABSTRACT

Eleven 6950 tined endocardial ventricular bipolar leads were chronically implanted in canines. The objectives of this in vivo study were to evaluate the qualities of nondislodgement, nonperforation, ease of handling and repositioning of this lead system. Stimulus thresholds, source impedances and intracardiac signal data were collected at implant and at monthly intervals up to four months for comparison to existing marketed lead systems. Due to the problems encountered with animal survival and test lead quality no recommendations regarding human implantibility of the 6950 tined endocardial lead were generated from this study.

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INTRODUCTION

A preclinical four month* study was conducted of the 6950 bipolar endocardial lead system. The request for this *in vivo* study was generated by Maria Rose of the Cardiovascular Leads Research and Engineering Department to support the claims of the 6950 lead's safety, efficacy and reliability. The 6950 lead is a redesign of the 6901 ventricular endocardial lead system. This redesign consisted of physical modification involving removal of the distal insulator flange and the addition of four 0.400" tines at 0.38" from the lead tip.[1] The tines were added in an attempt to improve the 6950 lead's dislodgement and non-perforation characteristics without sacrificing low thresholds. The tined lead was not to impact the ease of lead passage or positioning/repositioning attempts at initial implant. The electrical and mechanical specifications of the 6950 bipolar lead system are identical to those of the 6901 bipolar lead system.

Pursuant to [illegible] as provided in [illegible] Protective Orders.

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* Implant was to have been of six month duration, according to experimental design (memo #284:NF, 1976).

METHODOLOGY

Implant: Eleven 6950 leads were implanted individually in pre-conditioned mongrel dogs weighing at least seventeen kilograms. Each animal under went a right jugular venotomy. The leads were passed into the right ventricle and positioned in the apex with the aid of fluoroscopy. Attempts to perforate the myocardium were made at this point. The lead was again positioned in the apex of the right ventricle. Good lead placement was verified with threshold measurements. Initial placement, perforation attempts and repositioning were video taped (tape #'s 5, 6 and 7, 1976).

Subjects were then transferred to another operating room where the lead connector end was tunneled subcutaneously to a percutaneous threshold analyzer (PTA) that in turn was connected to an implanted 5950/5954 pulse generator by two lead extenders. The pulse generator was set at 100 bpm. The animals then underwent a right thoracotomy and were put into heartblock by electro-cautery through a purse-string incision in the right atrium.

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Threshold measurements, source impedances and cardiac signals were collected via the PTA. The pulse generator rate and pulse width were also recorded and x-rays taken of the lead/pulse generator system.

Monitoring: Monitoring was done at monthly intervals for four (4) months. The animals were prepped over the PTA, pre-anesthetized with Surital and maintained on gas inhalation. Threshold measurements, source impedances and cardiac signals were acquired via the PTA. Rate and pulse width of the implanted pulse generator were also acquired to assure proper pulse generator function.

Terminations: Following the final monitoring acquired directly from the lead connector pins, the animals were euthanatized with Sleep Away and necropsied. Any evidence of perforation or damage was noted and recorded on the Gross Pathology Data sheet. Tissue specimens were taken from the electrode sites and from a non-stimulated area of the heart for histopathologic evaluation.

RESULTS

Tables and graphs are presented of time (acute,4,8,12&16 weeks) vs. ($\bar{x} \pm SD$) of:

	table#	graph#
Source Impedances	1	1
Voltage @ Threshold	2	
unipolar configuration		2
bipolar configuration		3
Energy @ Threshold	3	
unipolar configuration		4
bipolar configuration		5

The final pathology report is divided into sections dealing with specific study objectives, comments and histopathology data:

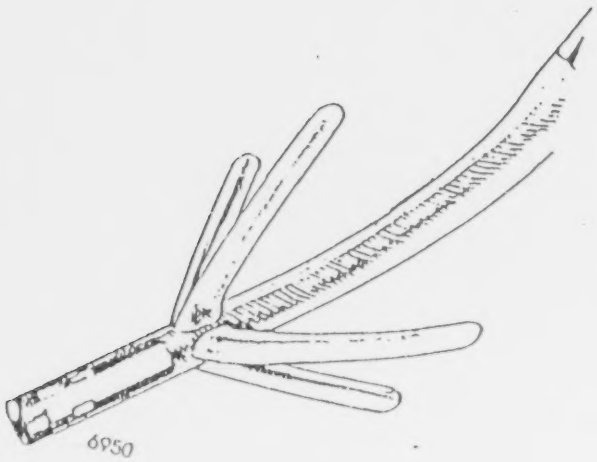
Nondislodgement
Nonperforation
Repositioning
Mechanical/Surgical Handling
AV Involvement
Pathology Summary @ Lead Site
Figure #1 Dissection of Right Ventricle
Figure #2 Cross Section of Heart
Figure #3 Cross Section Through Ventricles

The histopathology data was broken down into three groups of five animal each vs. time:

Group I study time≤6 days
Group II three weeks≤study time≤10 weeks
Group III eight weeks≤study time≤16 weeks

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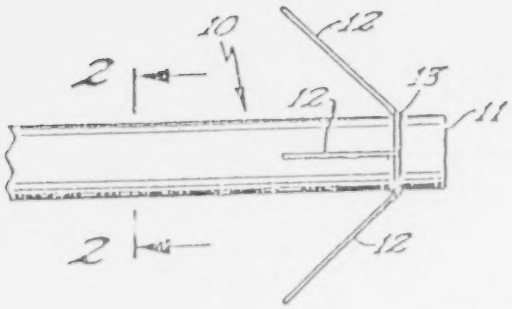
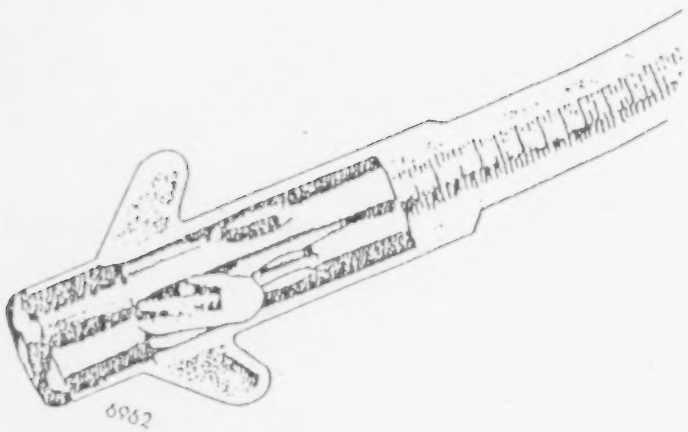
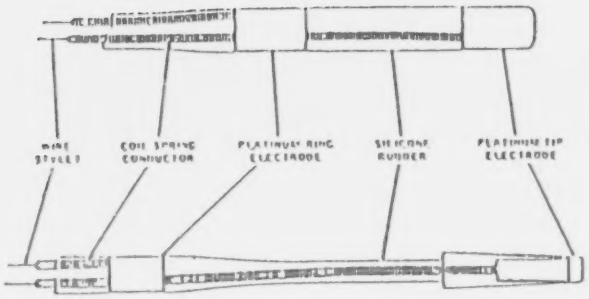


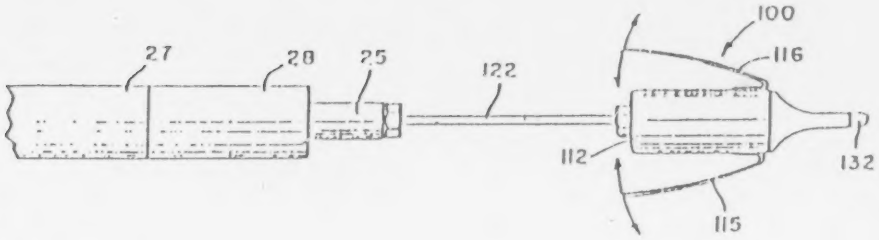
FIG. 1 OF '501 PATENT



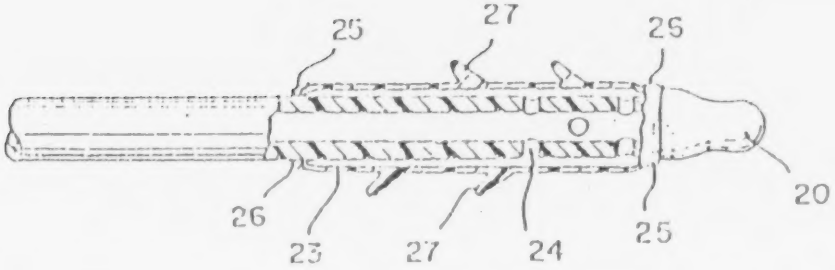
Standard tip and Flange-tip Bipolar Endocardial Leads



Nasor



Klieman



Fountain

